DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Proposed Rule to Revoke Use of Partially Hydrogenated Oils in Foods

Docket No. FDA- FDA-2019-N-4750

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

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Executive Summary

~~FDA is proposing a regulatory amendment that will~~This rule would, if finalized remove references to partially hydrogenated oils (PHOs) from our regulations for peanut butter, canned tuna, menhaden oil, fish oil, and rapeseed oil. ~~In conjunction with this,~~ FDA is also proposing to revoke all prior sanctions for the use of PHOs in margarine, shortening, and bread, buns, and rolls. ~~We are taking this~~This action is being taken because PHOs are associated with increased risk of coronary heart disease (CHD). ~~Following~~ This action aligns with the FDA's 2015 declaratory order ~~revoking~~that revoked the "generally recognized as safe" (GRAS) status of ~~PHOs, there remain few products in the market that continue to use PHOs in their food preparations. While the volume of PHO-containing products has declined substantially, FDA believes this action aligning our regulations with the 2015 Order to revoke the GRAS status of PHOs and revoking prior-sanctioned uses based on current scientific knowledge regarding the PHOs health risks will result in food products that will no longer contain~~ PHOs.

~~The quantifiable costs of removing PHO-containing foods from the market include those of reformulating products that continue to use PHOs, relabeling products~~We estimate that the quantifiable benefits of this rule will accrue from potential reduction of the number of coronary heart disease cases resulting from less use of PHO-containing ingredients. The estimated benefits discounted at seven percent over a 20-year period yields the mean present value of $652 million, or annualized total of $61.54 million. We quantify the costs to industry and consumers resulting from removal of PHO-containing foods from the market. These include the costs of product reformulation, relabeling, changing recipes for some foods, finding substitute ingredients and costs associated with changes in functional and sensory product properties, such as taste, texture, and product shelf life. ~~The expected benefits of this rule will accrue from potential reduction of number of coronary heart diseases resulting from the use of PHO-containing ingredients. The estimated net benefits discounted at seven percent over 20-year period yields the mean present value of $2.1 billion, or annualized total of $206.5~~

~~million. Finally, the~~The cost of this rule relative to gradual voluntary removal of PHOs was estimated at annualized primary value of $~~25~~24.5 million with a lower bound estimate of $~~13~~20.8 million and an upper bound estimate of $~~40~~29.7 million. These estimates are discounted at seven percent over a 20-year period.

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I. Introduction and Summary

A. Introduction

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, Executive Order 14094, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4).

Executive Orders 12866, 13563, and ~~13563~~14094 direct us to assess all costs ~~and~~, benefits, and transfers 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 believe that this proposed rule is a significant regulatory action as defined by Executive Order 12866.~~Rules are "significant" under Executive Order 12866 Section 3(f)(1) (as amended by Executive Order 14094) if they "have an annual effect on the economy of $200 million or more (adjusted every 3 years by the Administrator of [the Office of Information and Regulatory Affairs (OIRA)] for changes in gross domestic product); or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities." OIRA has determined that this proposed rule is not a significant regulatory action as defined by Executive Order 12866 Section 3(f)(1).

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The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this rule may require some small business entities to undertake costly reformulations, we find that the

proposed rule will 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 proposing~~for "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 $~~165~~177 million, using the most current (~~2021~~2022) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

B. Summary of Benefits and Costs

The benefits of this proposed rule are expected to accrue from the number of ~~coronary heart diseases~~CHDs averted from discontinued use of foods made with PHOs. The removal of PHO-containing foods from the marketplace will limit their access by most consumers. Such action will protect the public by reducing the health risk of developing CHD and improving population health~~.~~ among those who would otherwise consume products containing PHOs. Continual use of PHOs is associated with increased ~~coronary heart disease~~CHD and cardiovascular diseases~~.~~ (CVDs). Per capita higher intake of PHOs can lead to elevated risk of ~~coronary heart disease~~CHD and ~~cardiovascular diseases~~CVD among the U.S. population. Therefore, FDA notes that the benefit of this rule relative to baseline market conditions are expected to decrease over time as PHO containing products exit the marketplace. The annualized benefits of this rule discounted

at seven percent over a 20-year period is $~~206~~61.5 million for the primary estimate with a lower bound of $~~66.7~~20.1 million and an upper bound of $~~404.2~~120.7 million.[1]

The quantified costs of the rule are from reformulating manufactured products currently produced with PHOs, relabeling products that contain PHOs, changing recipes for some PHO containing breads by retail bakeries, finding substitute ingredients~~. The quantified costs include consumer and producer surplus losses arising from changes to~~ as well as costs arsing from functional and sensory product properties of affected products such as taste and texture. Discounted at seven percent over a 20-year period, the annualized primary cost estimate of the rule is $~~25.0~~24.5 million with a lower bound estimate of $~~13.1~~20.8 million and an upper bound estimate of $~~40.3~~29.7 million. The costs and benefits of this rule are estimated relative to the baseline condition where business entities are assumed to remove PHOs voluntarily and gradually from marketplace.

Table 1 below presents a summary of costs and benefits of the proposed rule.

Table 1: Summary of Benefits, Costs and Distributional Effects of the Proposed Rule, in 2020 million Dollars

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized $millions/year	$~~206~~61.5	$~~66.7~~20.1	$~~404.2~~120.7	2020	7%	20 years	
		$~~196.7~~58.3	$~~63.6~~19.1	$~~384.9~~114.3	2020	3%	20 years	
	Annualized Quantified					7%		
						3%		
	Qualitative							
Costs	Annualized Monetized $millions/year	$~~25.0~~24.5	$~~13.1~~20.8	$~~40.3~~29.7	2020	7%	20 years	
		$20.~~7~~2	$~~10.7~~17.1	$33.62	2020	3%	20 years	
	Annualized Quantified					7%		
						3%		

[1] Estimates are based on methods 1 to 3 benefit paths as described in the benefits section. Method 1 represent the low estimate, method 2 the primary and method 3 is the high estimate.

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Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
	Qualitative							
Transfers	Federal Annualized Monetized $millions/year					7%		
						3%		
	From/To	From:			To:			
	Other Annualized Monetized $millions/year					7%		
						3%		
	From/To	From:			To:			
Effects	State, Local or Tribal Government: None Small Business: Potential impact on small business entities that are currently continuing to use or produce PHOs and PHO containing ingredients in their products. Wages: None Growth: None							

We request comment on our estimates of costs and benefits of this proposed rule.

II. Preliminary Economic Analysis of Impacts

A. Background

In the *Federal Register* of June 17, 2015 (80 FR 34650), FDA published a declaratory order announcing the final determination that there is no longer a consensus among qualified experts that PHOs are GRAS for any use in human food [Ref. 1]. For a discussion of the scientific and safety issues associated with PHOs, we refer readers to the declaratory order (80 FR 34650) and to our tentative determination that identified the human health risks associated with consumption of trans fats (see 78 FR 67169 at 67171 (November 8, 2013)).

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B. Need for Federal Regulatory Action

~~As described further in the 'Baseline' section, we expect that most consumers believe that all partially hydrogenated oils have been removed from the U.S. food supply. This creates an information asymmetry: consumers believe that their food will no longer contain PHOs, but some food may still contain PHOs, as described in the 'Purpose of the Proposed Rule' section and as evidenced by a recent study in Canada.~~ This proposed rule would remove all prior-sanctioned uses of partially hydrogenated oils (PHOs) in foods following the 2015 action by FDA to revoke the PHOs GRAS status. In June 2015, FDA published a declaratory order (Order) setting forth the final determination, based on the available scientific evidence and the findings of expert scientific panels, that there is no longer a consensus among qualified experts that PHOs, which are the primary dietary source of industrially produced trans fatty acids, are GRAS for any use in human food. FDA acknowledged that there could be some express uses of PHOs in foods recognized by "prior sanction" (and thus could not be regulated as a food additive). FDA stated that such uses would be addressed separately from the final determination. It was also stated that FDA would consider taking further action, including revising certain standards of identity that list PHOs as optional ingredients. FDA is therefore issuing this rule to completely eliminate the use of all PHOs including the 'prior sanctioned' uses. This step will remove the information gap and fully ban any use of PHOs not addressed through the 2015 PHO Declaratory Order.

The use of PHOs in food preparation has declined significantly in recent years. Consumption of PHO-containing products has also declined significantly, a trend that

started before the declaratory order was issued in 2015[~~Ref. 2~~][Ref. 2, 3]~~. FDA action is required due to this information asymmetry.~~

~~Even if consumers did know that some food still contained PHOs, regulation would still be required. With consumer knowledge but without this rulemaking, consumers would face a choice of studying ingredient lists on food labels to avoid PHOs or being exposed to the health risks from consuming trans fats. We believe that an informed consumer would choose to pay slightly higher food prices to avoid the time costs of label reading and the health risks of trans fat consumption presented by these substances. As shown in the "Analysis of Regulatory Alternatives" section, the costs of consumers reading labels would be much higher than the costs of reformulating the products that use these oils.~~

. However, FDA believes that without government intervention through this rule, it is unlikely that the markets will self-correct to achieve zero levels of PHO use in foods. Studies have shown that up to 84 percent of products declaring to contain no PHOs actually had PHO ingredients in their products [Ref. 4]. Therefore FDA views the need for this rule as the most efficient means to complete the required removal of PHO from the food supply due to the health concerns from continued consumption of PHO-containing products.

C. Purpose of the Proposed Rule

FDA is ~~proposing to amend~~amending our regulations and ~~revoke~~revoking prior sanctions for the use of PHOs in food in light of our 2015 determination that PHOs are no longer GRAS. These amendments would remove PHOs as an optional ingredient in the

standards of identity for peanut butter and canned tuna, and remove partially hydrogenated menhaden oil, fish oil, and rapeseed oil from FDA's regulations affirming food substances as GRAS. We are taking this action ~~considering our determination that~~ because PHOs ~~are~~were declared no longer GRAS~~.~~ for any use in human food in 2015. These existing regulations must therefore be amended to reflect current scientific knowledge~~. We are also proposing to revoke~~ and address any confusion about the regulatory status of PHOs. Additionally, we conclude that there are prior-sanctioned uses of PHOs in margarine, shortening, and bread, rolls, and buns, and ~~rolls to protect the public from consuming harmful substances.~~that these uses may be injurious to health. Therefore, we are proposing to revoke the prior sanction for the uses of PHOs in margarine, shortening, and bread, rolls, and buns.

D. Baseline Conditions

~~Because of the media coverage of~~ After FDA's 2015 ~~declaratory order~~ Order stating that PHOs are no longer GRAS, ~~we expect that most~~there was confusion among consumers ~~believe that all~~ and food manufacturers about whether the use of PHOs ~~have been removed from their food. Very few~~in certain food preparations was still allowed [Ref. 5, 6]. The FDA declaratory order did not change the 2003 trans-fat labeling requirement. We do not know how many consumers, if any, would ~~therefore~~ continue to read labels to search for PHOs after ~~that time, and consequently without this rulemaking they could suffer the health harms we show below. FDA recognizes that this rule is a necessary measure to align our regulations with~~ the ~~2015~~ declaratory order ~~and current scientific knowledge.~~became effective in June 2018. Studies have shown that the introduction of trans-fat food labeling resulted in significant declines in foods containing

partially hydrogenated oils [Ref. 2, 3]. Without this rulemaking, there may be some confusion as to whether prior-sanctioned use of PHOs are permitted in certain foods. This could result in unintended consumption of products containing PHOs and consequently increased health risks. If finalized, ~~the~~this rule will help ensure all PHO-containing foods and PHO ingredients, including prior sanctioned uses, are removed from the marketplace. It is anticipated that the rule will affect less than 2~~%~~ percent of domestically produced food products and/or imports. The products ~~likely~~ to be affected include food products whose preparation may involve the use of PHOs like peanut butter and canned tuna; the partially hydrogenated forms of menhaden oil, fish oil, and rapeseed oils which are listed in our current regulations; and foods that use prior-sanctioned PHO ~~containing~~ ingredients in their recipes or preparations ~~like~~including margarine, shortening and baking of bread, buns, and rolls.

Currently, the food industry continues to move away from use of PHOs in their food preparations, recipes, and baking ingredients. By the time this proposed rule is published, manufacturers and bakeries should have already removed all foods containing unauthorized uses of PHOs based on the compliance dates for FDA's ~~2015 declaratory order~~[2]~~.~~Order.[3] We do not believe that they would reformulate back to using PHOs.

The baseline for this estimate ~~is a future where~~assumes:

~~2 FDA specified June 18, 2018 as the compliance date for industry to cease manufacturing foods with most uses of PHOs. The compliance date for certain limited uses of PHOs in manufacturing was extended until June 18, 2019. All foods containing unauthorized uses of PHOs should have worked through distribution and sales of products in the food supply by the compliance date of January 1, 2021. See 83 FR 23358.~~

3 FDA specified June 18, 2018 as the compliance date for industry to cease manufacturing foods with most uses of PHOs. The compliance date for certain limited uses of PHOs in manufacturing was extended until June 18, 2019. All foods containing unauthorized uses of PHOs should have worked through distribution and sales of products in the food supply by the compliance date of January 1, 2021. See 83 FR 23358.

- The levels of trans fat from PHOs covered by this proposed rule are initially at their current levels ~~which is above~~of 4.6 g per day per person [Ref. 3, 7].
- Since the ~~minimum tolerable thresholds~~baseline PHO consumption levels are from the period prior to the 2015 FDA Declaratory order, we scale down the consumption of PHO products by 2/3 based on the declining trend in PHO use observed in market products.
- ~~Most consumers do not read labels or take any action to avoid consuming these sources of PHOs.~~
- ~~A small number of especially health-conscious consumers do read labels and encourage producers to stop using these sources of PHOs, resulting in their gradual voluntary removal from the food supply.~~

~~We calculate costs and benefits relative to this baseline[4]. It is unclear how quickly these PHOs would be phased out without FDA action. At one extreme, they might be completely removed within ten years. At another extreme, the current usage might continue indefinitely. Our best estimate based on studies and public comments is that these sources of PHOs will continue to be gradually removed from the food supply for some foreseeable future in the absence of FDA action [Ref. 3, 4].~~

~~4 When presenting our estimates of input values, we use average values for readability. The actual probability distribution used in the model is included in parentheses. In the 'Costs' and 'Benefits' sections, 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.~~

- The majority of consumers do not read labels or take any action to avoid consuming foods with PHO containing ingredients [Ref. 8]. Moreover, some consumers who read labels may not trust what the labels say, or may have limited understanding of healthy choices [Ref. 9].

We calculate costs and benefits relative to this baseline.[5] It is unclear how quickly any remaining PHOs would be phased out without FDA action. Our best estimate based on studies and public comments is that any remaining sources of PHOs will continue to be gradually removed from the food supply for some foreseeable future in the absence of FDA action [Ref. 3, 10].

E. Benefits of the Proposed Rule

When PHOs are removed from foods, this causes trans fatty acids (TFA) to be replaced with saturated fatty acids (SFA), monounsaturated fatty acids (MUFA), and/or polyunsaturated fatty acids (PUFA), in a different proportion based on the fat or oil that replaces the PHOs. Each of these replacements prevents health harm, but by a different amount.

This proposed rule~~, if finalized,~~ will cause prior-sanctioned uses of PHOs to be replaced with a replacement mix of fats and oils. Our estimates for replacement mix of fats and oils are based on a 2014 comment from the Grocery Manufacturers Association (GMA) and other FDA reports ~~[Ref. 5, 6, 7, 8]~~[Ref. 11, 12, 13]. These are as follows:

5 When presenting our estimates of input values, we use average values for readability. The actual probability distribution used in the model is included in parentheses. In the 'Costs' and 'Benefits' sections, 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.

- High oleic soy oil, 25 percent (triangular distribution 15%; 25%; 35%);
- Fully hydrogenated oils, 10 percent (triangular distribution 0%; 10%; 20%);
- Interesterified fats, 10 percent (triangular distribution 0%; 10%; 20%);
- High oleic sunflower oil, 5 percent (triangular distribution 0%; 5%; 10%);
- Butter, 1 percent (triangular distribution 0%; 1%; 2%);
- Lard, 5 percent (triangular distribution 0%; 5%; 10%);
- Tallow, 4 percent (triangular distribution 0%; 4%; 8%);
- Soy Oil, 5 percent (triangular distribution 0%; 5%; 10%);
- Cottonseed oil, 2.5 percent (triangular distribution 0%; 2.5%; 5%);
- Canola oil, 2.5 percent (triangular distribution 0%; 2.5%; 5%); and
- Palm oil, 30 percent (100% minus the sum of all other oils used).

The weighted average fatty acid profile of these replacement oils is about 1 percent TFA, 39 percent saturated fatty acid (SFA), 44 percent monounsaturated fatty acid (MUFA), and 16 percent polyunsaturated fatty acid (PUFA). We estimate the weighted average fatty acid profile of the PHOs currently being used to be 33 percent TFA, 22 percent SFA, 31 percent MUFA, and 14 percent PUFA. Therefore, as a result of PHO replacement, we estimate that the net change in average fatty acid profile for replacement oils compared with current PHOs will be: TFA content will decrease by about 33 percentage points, SFA will increase by about 17 percentage points, MUFA will increase by about 14 percentage points, and PUFA will increase by about 2 percentage points.

Because the average TFA content decreases by about 33 percentage points with replacement using this estimate, every three grams of PHO replacement results in one gram of TFA replacement. For every gram of TFA removed from the diet because of this action, we estimate that SFA will increase by 0.52 grams, MUFA will increase by 0.42 grams, and PUFA will increase by 0.06 grams.

1. FDA Quantitative Assessment

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~~FDA conducted a quantitative assessment of risk for prior-sanctioned uses of PHOs [Ref. 7, 8]. This risk assessment presented estimates of the expected increase in coronary heart disease and cardiovascular disease due to the prior-sanctioned use of PHOs in margarine and shortening being added into foods. The risk assessment was based on the estimated mean per capita intake of industrially produced trans fatty acids of 0.164 grams per person per day (or 0.0739 percent of total dietary energy) from prior-sanctioned uses of PHOs in margarine and shortening in the U.S. population[6].~~

~~The risk assessment calculates what would happen if PHO amounts in the prior-sanctioned uses were increased to the levels observed before the 2015 declaratory order[7]. We estimate that the current levels of PHOs in these uses are less than 5 percent of what they were before the declaratory order. Correspondingly, we estimate that this rule has the potential to prevent at least 5% percent of the health harm described in the risk assessment [Ref. 7, 8].~~

~~6 The list of foods containing prior-sanctioned uses of PHOs include ingredients used in baked goods such as bread, rolls, and buns.~~
~~7 It is unlikely that PHO levels would increase that much, even if it were legal to do so, because of increased awareness of health risks associated with use of PHOs, and manufacturers responses to consumers' health concerns.~~

FDA conducted a quantitative assessment of health risks associated with trans-fat exposure from prior-sanctioned uses of PHOs. This risk assessment used methodology very similar to the methodology used in FDA's risk assessment for the 2015 final determination and was based on data from controlled feeding studies and prospective observational (i.e., epidemiological) studies. Key studies that first established a link between trans-fat intake and adverse effects on blood lipoproteins were reported in the early 1990s by Mensink and Katan (1990)[Ref. 14] and Zock and Katan (1992)[Ref. 15]. These two studies were based on randomly selected healthy adults that participated in feeding trials to compare the effects of diets providing the same amount of energy from either saturated fatty acids, trans fatty acids, or cis-monounsaturated and/or cis-polyunsaturated fatty acids on serum lipoprotein levels in humans. The studies used General Linear Models to analyze their data while applying Benferroni or Tukey methods[8] to generate confidence intervals for variables whose coefficients were statistically significant. Both studies showed the effect of trans fatty acid intake was adverse with respect to both LDL-C and HDL-C when compared with cis-monounsaturated or cis-polyunsaturated fatty acids. Because of the unfavorable effect on HDL-C, the results showed that trans fatty acid intake was more adverse than that of saturated fatty acids.

As additional controlled feeding trials were conducted over time, scientists examined the combined results in meta-analyses. In a meta-analysis study by Ascherio et

8 Both Bonferroni and Tukey methods use pairwise approach in compariring coefficients showing significant diet effects ($p<0.05$) to generate reliable confidence intervals. The Bonferroni technique is a more powerful method for handling estimations of small chance error in multiple testing. Tukey method on the other hand is used in analysis of variance (ANOVA) to generate confidence intervals for large numbers of means. The feeding trials concluded that one percent of dietary energy from trans fatty acids was associated with increased LDL cholesterol by about 0.6 mg/dl (0.015 mmol/l) relative to oleic or linoleic acid.

al in 1999 that examined plasma LDL:HDL ratios, a known risk factor for CHD, the authors concluded, "these studies provide definitive evidence that trans fatty acids raise this ratio more than do saturated fatty acids." [Ref. 16].

Meta-analyses were also conducted using epidemiological studies. One such study was reported by Mozaffarian and Clarke in 2009 which performed a meta-analysis of the effects of trans fats on blood lipids and lipoproteins in controlled dietary trials, and association of habitual trans fatty acids consumption with CHD outcomes in prospective cohort of studies[Ref. 17]. The study performed a multivariate regression analysis[9] based on reviewed studies that reported a positive relationship between increased LDL and cardiovascular heart disease due to TFAs intake. The study further calculated the CHD risk effects from replacing 7.5 percent of energy from three different partially hydrogenated vegetable oils with other replacement fats and oils such as butter, lard, palm or vegetable oils. They concluded that replacing 7.5 percent of energy from TFAs significantly decreased CHD risks by up to 19.8 percent depending on the type of replacement oils used[Ref. 17]. They also concluded that accounting for summed effects of TFAs on multiple CHD risk factors provided more accurate estimates of potential risk reduction than considering each risk factor in isolation[Ref. 17].

In addition, results from other studies have also been very consistent regarding the effect of industrial trans-fats intake and increased risk of CHDs [Ref. 18, 19]. Although these scientific studies do not prove the existence or magnitude of a causal relationship

9 The control variables included age, weight, duration of dietary intervention, intakes of TFAs, SFAs, MUFAs, PUFAs, protein dietary cholesterol and total energy, stratified by gender and inverse weight by the number of individuals in each trial. Coefficients from these analyses were used to asses the effects of isocaloric replacement of TFAs, for SFAs, MUFAs or PUFAs while also taking into account the consumption of each of the other dietary fats.

the results are consistent and supportive of the conclusions from controlled feeding studies regarding the direction of the effect of trans fat intake on blood lipids.

The evidence and conclusions of these studies form the foundation on which FDA based our quantitative risk assessments. This risk assessment presented estimates of the expected increase in CHD and CVD due to the prior-sanctioned use of PHOs in margarine and shortening being added into foods[Ref. 12]. The risk assessment was based on the estimated mean per capita intake of industrially produced trans fatty acids of 0.164 grams per person per day (or 0.0739 percent of total dietary energy) from prior-sanctioned uses of PHOs in margarine and shortening in the U.S. population[Ref. 20].[10]

The risk assessment calculates what would happen if PHO amounts in the prior-sanctioned uses were increased to the levels observed before the Order.[11] We estimate that use of PHOs declined from 6 percent prior to the pre-declaratory order period to less than 1 percent of all products reviewed after the declaratory order became effective. Following the declaratory order, we saw significant reduction in the use of industrially produced trans-fats as demonstrated by our search for PHO containing food products as declared on their product labels.[12] Correspondingly, we estimate that this rule, together with earlier FDA actions related to PHOs, has the potential to prevent over 95 percent of the health harm described in the risk assessment[Ref. 7, 13] . These estimates are based on the fact that industrially produced trans-fatty acids are known to cause adverse health effects.

10 The list of foods containing prior-sanctioned uses of PHOs include ingredients used in baked goods such as bread, rolls, and buns.
11 It is unlikely that PHO levels would increase that much, even if it were legal to do so, because of increased awareness of health risks associated with the use of PHOs, and manufacturers responses to consumers' health concerns.
12 See more details provided in section F of this RIA focusing on costs of this rule.

The risk assessment calculates the health effects of replacing trans fatty acids with either saturated fatty acids or monounsaturated fatty acids. These are the two main fats that will replace trans fats. In addition, a small but nonzero amount of trans fats will be replaced with polyunsaturated fatty acids. We used the numbers for this replacement from a previous PHO risk ~~assessments~~assessment conducted by FDA ~~[Ref. 6, 7, 8]~~[Ref. 1, 12, 21].

The risk assessment presents ~~four~~three methods of calculating the effect of oil replacement on ~~coronary heart disease (~~CHD~~)~~ or heart attacks as shown in Table 2. For each method, ~~we use that method's numbers to~~the worst case scenario to calculate the health result of the oil replacement described above~~.~~ were assumed. The scenarios were based on 2015 levels of consumption of PHOs prior to declaratory order.[13] The risk assessment also presents evidence that replacing PHOs will reduce other types of ~~cardiovascular disease~~CVD events, for example strokes. ~~For each method,~~Because these events have similar causes, we estimated a decrease in other ~~cardiovascular disease (CVD)~~CVD events proportional to the reduction in fatal heart attacks for each method.

Method 1 looks only at the health effects of *trans fats* on low-density lipoprotein (LDL) sometimes referred to as 'bad' cholesterol, a validated surrogate endpoint biomarker for ~~coronary heart disease~~CHD, as shown through controlled feeding trials. With these numbers, we estimate that replacing prior-sanctioned uses of PHOs will prevent about ~~10~~3 fatal heart attacks, ~~18~~6 nonfatal heart attacks, and ~~8~~3 other CVD events per year.

13 Since the consumption of PHOs prior to 2015 declaratory order were relatively higher, we estimate the benefits of this rule by assuming that the consumption of PHOs have already declined by 2/3 of the 2015 consumption levels. This assumption is informed by our market search for PHO containing products which we found to have declined by between 50 – 80 percent from the levels reported in 2015.

Method 2 combines the effects of Method 1 with the additional effects of *trans* fats on high-density lipoprotein (HDL) or 'good' cholesterol, a major CHD risk factor biomarker, as shown through controlled feeding trials. With these numbers, we estimate that replacing prior-sanctioned uses of PHOs will prevent about ~~31~~10 fatal heart attacks, ~~56~~18 nonfatal heart attacks, and ~~24~~8 other CVD events per year.

Method 3 combines the effects of Method 2 with the effects of trans-fatty acids (TFA) on a combination of emerging CHD risk factor biomarkers, as shown through controlled feeding trials. With these numbers, we estimate that replacing prior-sanctioned uses of PHOs will prevent about ~~61~~20 fatal heart attacks, ~~109~~36 nonfatal heart attacks, and ~~46~~15 other CVD events per year.[14]

~~Method 4 uses association of *trans* fats with CHD risk as shown through prospective observational studies. With these numbers, we estimate that replacing prior-sanctioned uses of PHOs will prevent about 166 fatal heart attacks, 294 nonfatal heart attacks, and 125 other CVD events per year.~~

Table 2. Base Estimates of Disease Prevention with Expected Oil replacement

Effect Calculation Method[15]	CHD Fatal ~~Events Prevented~~	CHD Nonfatal ~~Events Prevented~~	Other CVD ~~Events Prevented~~
Method 1: LDL	~~10~~3	~~18~~6	~~8~~3
Method 2: LDL + HDL	~~31~~10	~~56~~18	~~24~~8
Method 3: LDL + HDL + Others	~~61~~20	~~109~~36	~~46~~15
~~Method 4: Observational~~	~~166~~	~~294~~	~~125~~

~~Notes: 1.~~ Note: Low-density Lipoprotein (LDL) and High-density lipoprotein (HDL) refer to cholesterol levels.

14 In addition to these three methods, some studies have used observational approach which associates trans-fat contents with CHD risks. Because of potential errors of omitted variables inherent in this approach, we refrain from using it in our current estimates.

15 Details of these methods can be found in FDA's final rule on trans-fat labeling (68 FR 41434 at 41466 to 41492) for Methods 1 & 2, and for ~~Methods~~Method 3 ~~& 4~~ in Mozaffarian D. & R. Clarke (2009) "Quantitative effects on cardiovascular risk factors and coronary heart disease risk of replacing partially hydrogenated vegetable oils with other fats and oils"," European Journal of Clinical Nutrition, Vol. 63, S22-S33.

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~~2. Other CVD events refer to non-heart attacks. These are strokes or heart conditions with similar health effects.~~

As described in the 'Baseline' section, we do not anticipate that consumption of these PHOs will remain unchanged. We anticipate a baseline of gradual removal of these PHOs, meaning that the benefits of this rule relative to the baseline will decrease over time. As an example, Table 3 shows the expected benefit path, using Method 1 numbers.

Table 3. Benefit Path, Method 1

Years after Effective Date of Rule (from 2023-2042)	Baseline Removal Relative to Year 1 PHO Content	Fatal CHD Cases Prevented	Nonfatal CHD Cases Prevented	Other CVD Cases Prevented
1	0%	0	0	0
2	5%	0	0	0
3	10%	0	0	0
4	15%	~~9~~ 3	~~15~~5	~~7~~2
5	20%	~~8~~ 3	~~14~~5	~~6~~2
6	25%	~~8~~ 2	~~14~~4	~~6~~2
7	30%	~~7~~ 2	~~13~~4	~~6~~2
8	35%	~~7~~ 2	~~12~~4	~~5~~2
9	40%	~~6~~ 2	~~11~~4	~~5~~2
10	45%	~~6~~ 2	~~10~~3	~~4~~1
11	50%	~~5~~ 2	~~9~~3	~~4~~1
12	55%	~~5~~ 1	~~8~~3	~~4~~1
13	60%	~~4~~ 1	~~7~~2	~~3~~1
14	65%	~~4~~ 1	~~6~~2	~~3~~1
15	70%	~~3~~ 1	~~5~~2	~~2~~1
16	75%	~~3~~ 1	4 1	~~2~~1
17	80%	~~2~~ 1	4 1	~~2~~1
18	85%	~~2~~ 0	~~3~~1	~~1~~0
19	90%	~~1~~ 0	~~2~~1	~~1~~0
20	95%	~~0~~	~~1~~0	0
Average		**~~4~~1**	**~~7~~2**	**~~3~~1**

~~3.~~2. Quantifying monetary benefits from averted mortality and morbidity

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The benefits of this proposed rule all occur in the future, so the monetized values of these future benefits must be converted into present values. We use seven percent and three percent discount rates for this conversion in our estimate. Some example calculations are presented only at the seven percent discount rate for clarity. However, all calculations were also done with a three percent discount rate, and we present the summary of results under all four methods in Table 7. All other calculations in Tables 4, 5 and 6 are based on method 1 approach and are only presented for illustrative purposes. We use the value of statistical life (VSL) and the value of quality adjusted life years (VQALYs) to estimate benefits from avoided mortality and morbidity respectively. These estimates are presented separately as described below.

~~4.~~3. Benefits from avoided mortality caused by heart attacks

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We value the reduction in mortalities from the consumption of foods with PHO-containing ingredients using the VSL approach, as recommended by HHS guidelines ~~[Ref. 9].~~[16] VSL estimates do not represent the dollar value of a person's life but instead represents the amount individuals are willing to pay for small reductions in mortality risk. VSL uses a range of estimates to measure the monetary value of reduced mortality. The estimates of VSL following the final rule's effective date (for the purpose of this analysis, we hereby assume the rule to be effective in 2023) range from $5.5 million to $17.8 million with a central estimate of $11.7 million. These estimates are presented in 2020 dollars. The first year and all subsequent values are adjusted for the projected income

16 See Office of the Assistant Secretary for Planning and Evaluation (ASPE), U.S. Department of Health and Human Services (2016), Guidelines for Regulatory Impact Analysis: https://aspe.hhs.gov/sites/default/files/private/pdf/242926/HHS_RIAGuidance.pdf.

growth.[17] ~~.~~ Currently, the Congressional Budget Office (CBO) projects a real income growth of 0.8 percent per year through year 2051[18].

Table 4 below presents the summary of our estimates based on expected number of PHO-related fatality cases to be avoided over a 20-year period. As described in the ~~'Baseline'~~Baseline section, we do not anticipate that consumption of these PHOs will remain unchanged. We assume a baseline of gradual removal of these PHOs, meaning that the benefits of this rule relative to the baseline decreases over time. Table 4 shows this expected benefit path, using Method 1 numbers as an example. The VSL values are multiplied by corresponding estimated number of avoided premature deaths related to use of PHO-containing products under Method 1. We present the primary, low, and high estimates based on prevented fatality cases with total annualized estimates at both 3 percent and 7 percent. The monetized primary estimate of prevented fatal heart attack annualized at 3~~%~~ percent discount rate is averaged at $12.~~02~~14 million and nearly $12.~~18~~31 million at 7~~%~~ percent discount rate.

Table 4. Monetized Benefits based on Method 1: LDL approach (estimates in millions of 2020 dollars)

Years after Effective Date of Rule (from 2023-2042~~)~~	Baseline Removal Relative to Year 1 PHO Content	Fatal CHD Cases ~~Prevented~~[π]Prevented[π]	Primary Estimate	Low Estimate	High Estimate
1	0%	~~-~~0	$0.~~00~~	$0.~~00~~	$0.~~00~~
2	5%	0	$0.~~00~~	$0.~~00~~	$0.~~00~~
3	10%	0	$0.~~00~~	$0.~~00~~	$0.~~00~~

[17] The department of Health and Human Services provides VSL values for changes in mortality risk occurring in 2020 through 2049: https://www.aspe.hhs.gov/sites/default/files/2021-07/hhs-guidelines-appendix-d-vsl-update.pdf? (D-11)

[18] Congressional Budget Office. "The 2021 Long-Term Budget Outlook." Table A-2. Average Annual Values for Economic Variables That Underlie CBO's Extended Baseline Projections: Growth of Real Earnings per Worker, 2021-2051. https://www.cbo.gov/publication/57038#_idTextAnchor040 Accessed November 2022. (34)

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4	15%	~~9~~ 3	~~$100.28~~ $33.43	~~$47.14~~ $15.71	~~$152.57~~ $50.86
5	20%	~~8~~ 3	~~$94.39~~ $31.46	~~$44.37~~ $14.79	~~$143.59~~ $47.86
6	25%	~~8~~ 2	~~$88.49~~ $29.50	~~$41.60~~ $13.87	~~$134.62~~ $44.87
7	30%	~~7~~ 2	~~$82.59~~ $27.53	~~$38.82~~ $12.94	~~$125.65~~ $41.88
8	35%	~~7~~ 2	~~$76.69~~ $25.56	~~$36.05~~ $12.02	~~$116.67~~ $38.89
9	40%	~~6~~ 2	~~$70.79~~ $23.60	~~$33.28~~ $11.09	~~$107.70~~ $35.90
10	45%	~~6~~ 2	~~$64.89~~ $21.63	~~$30.50~~ $10.17	~~$98.72~~ $32.91
11	50%	~~5~~ 2	~~$58.99~~ $19.66	~~$27.73~~ $9.24	~~$89.75~~ $29.92
12	55%	~~5~~ 1	~~$53.09~~ $17.70	~~$24.96~~ $8.32	~~$80.77~~ $26.92
13	60%	~~4~~ 1	~~$47.19~~ $15.73	~~$22.18~~ $7.39	~~$71.80~~ $23.93
14	65%	~~4~~ 1	~~$41.29~~ $13.76	~~$19.41~~ $6.47	~~$62.82~~ $20.94
15	70%	~~3~~ 1	~~$35.39~~ $11.80	~~$16.64~~ $5.55	~~$53.85~~ $17.95
16	75%	~~3~~ 1	~~$29.50~~ $9.83	~~$13.87~~ $4.62	~~$44.87~~ $14.96
17	80%	~~2~~ 1	~~$23.60~~ $7.87	~~$11.09~~ $3.70	~~$35.90~~ $11.97
18	85%	~~2~~ 0	~~$17.70~~ $5.90	~~$8.32~~ $2.77	~~$26.92~~ $8.97
19	90%	~~1~~ 0	~~$11.80~~ $3.93	~~$5.55~~ $1.85	~~$17.95~~ $5.98
20	95%	~~1~~ 0	~~$5.90~~ $1.97	~~$2.77~~ $0.92	~~$8.97~~ $2.99
~~Net present~~Present value at 3%			$~~689.91~~229.97	$~~324.32~~108.11	$~~1,049.60~~349.87
~~Net present~~Present value at 7%			$~~497.83~~165.94	$~~234.02~~78.01	$~~757.38~~252.46
Annualized at 3%			$15.~~46.37~~	$~~21.80~~7.27	$~~70.55~~23.52
Annualized at 7%			$~~46.99~~15.66	$~~22.09~~7.36	$~~71.49~~23.83
Annualized value per case at 3% discount			$12.~~02~~ 14	$5.~~65~~71	$18.~~29~~48
Annualized value per case at 7% discount			$12.~~18~~31	$5.~~73~~78	$18.~~54~~72

~~*~~π Note that because of rounding in this and subsequent tables estimates may not sum up for each column.

~~5.~~4. Benefits from avoided morbidity

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In addition to benefits accruing from avoided mortality, there are also other benefits resulting from avoided morbidity. High level consumption of trans-fats has been associated with increased heart attacks or other cardiovascular diseases like stroke. Improvements in health-related quality of life after heart attack or other cardiovascular diseases can be variable depending on the severity of the disease~~[Ref. 9, 10]~~[Ref. 22, 23]. We therefore present our estimates of avoided morbidity from heart attack and from other cardiovascular diseases separately below.

a) Benefits from ~~verted~~averted morbidity caused by Heart Attacks

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Each nonfatal heart attack causes lowered quality of life for the rest of the victim's average 13 years of life. Based on literature, the average annual loss in Quality Adjusted Life years (QALYs) due to heart attack is estimated at 0.18 ~~[Ref. 11, 12]~~[Ref. 7, 24]. The present discounted value of this QALY loss is 1.44 for the seven percent and 1.98 for the three percent discount rate. We use estimates of the value per quality-adjusted life year from the Department of Health and Human Services (HHS) guidelines~~[Ref. 13] to monetize the quality of adjusted life year gained due to prevention of nonfatal heart attack.~~[19] to monetize the quality of adjusted life year gained due to prevention of nonfatal heart attack. With the assumption that this rule will become effective in the year 2023, we use 2023 VQALY primary estimate of $990,000 with $460,000 and $1,510,000 as low and high estimates for the 7 percent discount rate. We also use the primary estimate of $590,000 with $280,000 and $910,000 as low and high estimates for the 3 percent discount rate. We multiply these values with the survival QALY saved for impacts occurring in 2023. Like the mortality estimates, our calculations are also adjusted for the projected income growth as recommended in HHS guidelines. We use the same income growth of 0.8 percent per year as projected by CBO through year 2051. For illustrative purposes, Table 5 below presents a summary of our estimates of benefits resulting from prevented heart attacks.

Table 5: Monetized Benefits for nonfatal coronary heart diseases (CHD) prevented based on Method 1: LDL approach

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19 See ASPE/HHS Guidelines: https://aspe.hhs.gov/sites/default/files/private/pdf/242926/HHS_RIAGuidance.pdf.

Years after Effective Date of Rule (from 2023-2042~~)~~	Baseline Removal Relative to Year 1 PHO Content	Nonfatal ~~CHDs*~~CHDs[π]	Monetized Primary Estimates of VQALY in millions 2020 dollars	
		Nonfatal CHDs cases prevented	Nonfatal CHDs at 3%	Nonfatal CHDs at 7%
1	0%	0	~~$0.00~~ $-	~~$0.00~~ $-
2	5%	0	~~$0.00~~ $-	~~$0.00~~ $-
3	10%	0	~~$0.00~~ $-	~~$0.00~~ $-
4	15%	~~15~~5	~~$17.80~~ $5.93	~~$21.72~~ $7.24
5	20%	~~14~~5	~~$16.75~~ $5.58	~~$20.45~~ $6.82
6	25%	~~13~~4	~~$15.71~~ $5.24	~~$19.17~~ $6.39
7	30%	~~13~~4	~~$14.66~~ $4.89	~~$17.89~~ $5.96
8	35%	~~12~~4	~~$13.61~~ $4.54	~~$16.61~~ $5.54
9	40%	~~11~~4	~~$12.57~~ $4.19	~~$15.33~~ $5.11
10	45%	~~10~~3	~~$11.52~~ $3.84	~~$14.06~~ $4.69
11	50%	~~9~~3	~~$10.47~~ $3.49	~~$12.78~~ $4.26
12	55%	~~8~~3	~~$9.42~~ $3.14	~~$11.50~~ $3.83
13	60%	~~7~~2	~~$8.38~~ $2.79	~~$10.22~~ $3.41
14	65%	~~6~~2	~~$7.33~~ $2.44	~~$8.94~~ $2.98
15	70%	~~5~~2	~~$6.28~~ $2.09	~~$7.67~~ $2.56
16	75%	~~4~~1	~~$5.24~~ $1.75	~~$6.39~~ $2.13
17	80%	~~4~~1	~~$4.19~~ $1.40	~~$5.11~~ $1.70
18	85%	~~3~~1	~~$3.14~~ $1.05	~~$3.83~~ $1.28
19	90%	~~2~~1	~~$2.09~~ $0.70	~~$2.56~~ $0.85
20	95%	~~1~~0	~~$1.05~~ $0.35	~~$1.28~~ $0.43
~~Net present~~Present value			~~$122.46~~40.82	~~$149.44~~35.95
Annualized			~~$8.23~~2.74	~~$10.05~~3.39
Annualized value per case			~~$~~1.~~20~~21	~~$~~1.~~46~~50

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b) Benefits from averted morbidity caused by other CVDs

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Next, we estimate benefits from avoided morbidity caused by other cardiovascular (CVD) illnesses. We believe that most CVD events prevented by this rule that are not heart attacks will be strokes or will have similar health effects. ~~The average first-ever stroke causes a loss of 5.1 quality-adjusted life-years when discounted at three percent, and a loss of 3.2 QALYs when discounted at seven percent [Ref. 12, 13].~~Based

on literature, the average annual loss in Quality Adjusted Life Years (QALYs) due to heart attack is estimated at 0.21 [Ref. 23]. We use this average to generate the QALYs lost for individuals assumed to survive for up to 7.1 years after their first stroke. The average first-ever stroke causes an average loss of 1.49 quality adjusted life-years when discounted at three percent and a loss of 1.08 QALYs when discounted at seven percent [Ref. 23]. These QALY estimates are used to calculate the monetary value of quality-of-life gained from preventing the average ~~stoke~~stroke by multiplying with VQALY estimates as outlined in HHS guidelines. Again, assuming the rule will become effective in the year 2023, we follow the same procedures as described in preceding subsection using 2023 VQALY primary estimate of $990,000 with a low and high $460,000 and $1,510,000 respectively for the 7 percent discount rate. We also use the primary estimate of $590,000 with low and high of $280,000 and $910,000 estimates for the 3 percent discount rate. Like in the preceding subsection these are multiplied with the survival QALY saved of ~~5.~~1.49 and ~~3.2~~1.08 for three and seven percent discount rates. Table 6 below presents a summary of our estimates of benefits resulting from prevented heart attacks based on Method 1 impacts as described above. As in preceding calculations, these estimates are adjusted for inflation, real income growth and are presented in 2020 dollars.

Table 6: Monetized Benefits for nonfatal cardiovascular diseases (CVD) prevented based on Method 1: LDL approach

Years after Effective Date of Rule (from 2023-2042~~)~~	Baseline Removal Relative to Year 1 PHO Content	Other nonfatal ~~CVDs*~~CVDs[π]	Monetized Primary Estimates of VQALY in millions 2020 dollars

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		Other nonfatal CVDs cases prevented	Nonfatal CVDs at 3%	Nonfatal CVDs at 7%
1	0%	0	$0.00	$0.00
2	5%	0	$0.00	$0.00
3	10%	0	$0.00	$0.00
4	15%	62	$19.44 $1.89	$20.47 $2.30
5	20%	62	$18.30 $1.78	$19.27 $2.17
6	25%	62	$17.16 $1.67	$18.06 $2.03
7	30%	52	$16.01 $1.56	$16.86 $1.90
8	35%	52	$14.87 $1.45	$15.65 $1.76
9	40%	52	$13.73 $1.34	$14.45 $1.63
10	45%	41	$12.58 $1.23	$13.25 $1.49
11	50%	41	$ $1.11.44	$12.04 $1.35
12	55%	31	$10.29 $1.00	$10.84 $1.22
13	60%	3 1	$9.15 $0.89	$9.63 $1.08
14	65%	31	$8.01 $0.78	$8.43 $0.95
15	70%	21	$6.86 $0.67	$7.23 $0.81
16	75%	21	$5.72 $0.56	$6.02 $0.68
17	80%	21	$4.58 $0.45	$4.82 $0.54
18	85%	10	$3.43 $0.33	$3.61 $0.41
19	90%	10	$2.29 $0.22	$2.41 $0.27
20	95%	0	$1.14 $0.11	$1.20 $0.14
Net presentPresent value			$133.7713.04	$140.8311.43
Annualized			$8.990.88	$9.591.08
Annualized value per case			$1.310.91	$3.261.12

*π Numbers may not sum up in each column because of rounding

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Tables 7 shows the breakdown of monetized benefits by type, and the path of benefits, for all fourthree methods outlined. Methods 2 to 43 have proportionately larger monetized values because of estimated larger effects for the targeted populations.

Table 7. Annual Benefits estimates for the four methods compared to unchanged consumptions, estimates in millions of 2020 Dollars

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	Method 1: LDL *Low*	Method 2: LDL + HDL *Primary*	Method 3: Other Markers	Method 4: Observational

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20. The observational method 4 is deemed as less likely scenario to align with baseline data following FDA's June 18,

						High					
Discount rate				*3%*	*7%*		*7%*	*3%*	*3%*	*7%*	
Benefits from ~~averted~~avoided mortality caused by ~~heart attacks~~CHD[21]	~~$46.37~~	~~$46.99~~	~~$142.56~~	~~$144~~15.46	~~$28~~0.52 15.66	~~$284.~~2647.04	~~$763~~.384 7.67	$~~77~~392.57			~~$~~
Benefits from ~~averted~~avoided morbidity caused by ~~heart attacks~~to CHD[22]				$2.74	$3.39	~~$8.23~~ ~~18~~49	$10.49	~~$25.71~~16.52	$~~31.8~~020.42	~~$50~~.05	~~$6~~2.89 ~~$13~~4.99
Benefits from ~~averted~~avoided morbidity caused by ~~other cardiovascular diseases (~~Other CVDs~~)~~[23]				~~$8.99~~0.88	~~$9.59~~1.08	~~$28.38~~2.74	~~$30.283.~~37	~~$54.40~~5.25	$~~58.0~~46.46	~~$147.84~~	~~$15~~
Annualized Total				**~~$63.60~~ $19.08**	**$~~66.762~~0.14**	**~~$196.66~~ ~~$58.27~~**	**~~$206~~ $61.54**	**$~~384.97~~114.34**	**~~$404.20~~ $120.70**	**~~$1,046.21~~**	**~~$1,09~~**

5. Accounting for potential changes in near-term consumer utility

We recognize that our benefit estimates do not explicitly account for potential changes in utility beyond the health benefits estimated above. This rule will require food manufacturers to reformulate their recipes and replace PHO containing ingredients with

~~2018, compliance date for industry to cease manufacturing foods with most uses of PHOs. More details can be found in 83 FR 23358. It is anticipated that the impact of this move by FDA would make method 4 unrealistic option. Methods 2 is therefore included in our summary table as primary estimate with method 1 and 3 representing the low and high estimates respectively.~~

21 Coronary heart disease (CHD) estimates for fatal outcomes are based on value of statistical life (VSL)

22 CHD estimates for nonfatal outcomes are based on monetized quality adjusted life years (VQALYs)

23 Other nonfatal cardiovascular diseases (CVDs) with larger QALY estimates mostly assumed to be associated with stroke related conditions.

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non-PHOs. Given that consumers have advocated for the withdrawal of PHOs from the market, it is possible that they will experience an overall utility gain (including both relatively long-term health benefits and any near-term effects) [Ref. 25, 26]. There may be some non-quantified benefits from slightly improved product taste and quality which has the potential to increase near-term utility due to improved PHO-free products.On the other hand, these reformulations may also result in a loss in near-term utility due to slight changes in taste, texture and other functional properties. Bauner et al.'s testing of these hypotheses using microwave popcorn data [Ref. 27] suggests that a PHO ban may have approximately the same near-term consumer welfare effect as a 17-percent increase in price. However, an extrapolation from microwave popcorn estimates would introduce uncertainty into an analysis of the effects of PHO removal from the products subject to this proposed rule. Alternatively, and as a general matter, an internality percentage (representing the harm the consumers of PHOs impose on their future selves) could be multiplied by the preceding estimates of the proposed rule's health benefits to yield consumer welfare estimates that also encompass near-term utility reductions, in addition to the longer-term health improvements. We are unaware of any research literature that more directly (i.e., for the products affected by this proposed rule) quantifies near-term consumer utility changes, but such changes are important to account for. We request comment on whether such literature is available, and if not, how to use or improve upon the extrapolations discussed above.

F. Costs of the Proposed Rule

The estimated costs of removing these sources of PHOs from the food supply are derived from the following:

1. Reformulating manufactured products currently produced with the PHOs
2. Relabeling products currently produced with the PHOs
3. Changing recipes at retail bakeries
4. Increased costs of substitute ingredients
5. Changes in functional and sensory product properties, such as taste, texture, and shorter product shelf life

We estimate each cost separately in the sections below. For all costs, we calculate the difference in costs between the baseline scenario of gradual removal and the removal required by this proposed rule. Our estimates consider a scenario where business entities will have at least one year of transitioning from the use of PHO ingredients in consideration of the rule's publication date and the compliance date.

All costs reported are the differences between the estimated costs required by this proposed rule and the estimated baseline costs, annualized over 20 years at three and seven percent discount rates, in 2020 dollars. In each ~~Cost~~cost section, we present a table showing the estimated costs in each of the next 20 years under the baseline scenario and the proposed rule, along with their ~~net~~ present values and annualized values.

1. Food Manufacturer Reformulation Costs

Most *trans* fats from PHOs have already been taken out of the American diet as a result of FDA actions ~~[Ref. 14].~~taken prior to the declaratory order [Ref. 28]. The 2007 Report of Trans Fat Conference Planning group describes the available substitutes for PHOs, and recommends consideration for reformulation while also presenting case

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studies of successful reformulations ~~[Ref. 15].~~[Ref. 25] . A major producer of processed foods reported that reformulating in less than a year cost $25 million for 187 product lines, or $134,000 per product, and after the reformulation the products were fully competitive, with no significant change in price, consumer acceptance, or shelf life ~~[Ref. 15].~~[Ref. 25] .

It is possible that there would be no serious difficulties with replacing the remaining low erucic acid rapeseed (LEAR) and menhaden PHOs in processed, packaged foods, and that the knowledge gained in past reformulations and research into alternatives could be used to reformulate the remaining products at a low cost. However, reformulation of the remaining products may prove to be less economically feasible or technologically possible. We use the middle-ground estimate that reformulation is possible for all existing products but is expensive, and that half of the products (triangular distribution 0%; 50%; 100%) would require a critical reformulation and the remaining products a noncritical reformulation. A critical reformulation is one that requires extensive work, and a noncritical reformulation is a relatively simple ingredient substitution. ~~We request comment on this estimate.~~

~~We searched the FoodEssentials database which was recently renamed "Label Insight" for products that would be affected by these rules [Ref. 16].~~We searched the online Label Insight database, for products that would be affected by these rules.[24] Label Insight maintains information on products that have been in the market but does not indicate whether the products continue to be available in the market. The database can

24 See "*Partially hydrogenated oils"* at Label Insight (November 2020) https://www.labelinsight.com/

therefore contain inaccurate information on the stock of products that are actively selling. To overcome this limitation, we merged Label Insight data with proprietary data from market research firm, Information Resources, Inc (IRi) using the 13-digit universal product codes (UPCs). IRi Liquid Data is a comprehensive store-based scanner dataset providing UPC-level sales, product information, and brand name and manufacturer. IRi maintains data on products that are actively selling in the market at any given time of the year.[25] The data is based on weekly scan information of thousands of grocery, drug, and department stores sales data collected by their scanners [Ref. 17].[26] This included peanut butter, canned tuna, and bread, rolls, and buns that contained a PHO, as well as any product that contained menhaden oil, fish oil, rapeseed oil, or margarine or shortening that contained a PHO.[27] We only used data only on products available in the market after 2015 (from January 2016 to December 2019). Based on the number of labelsproducts with PHOs,labeled and industry comments that PHOs are used as processing aids in products without appearing on the labelsunlabeled PHO claims, we estimate that about 1,180 products (triangular distribution 600, 1,180, 1,800) will require critical or noncritical reformulation as a result of this rule [Ref. 5, 14, 18][Ref. 11, 28, 29].

We used the FDA reformulation cost model to calculate the average cost of a change in critical and noncritical minor ingredients [Ref. 19].[Ref. 30]. The average cost of these reformulations over a one-year time is about $50,000 for a non-critical

25 IRi scanner data is comparable to AC Nielsen scanner data. Each dataset tracks scanned sales at the national and local levels and use a statistically accepted projection methodology. However, the sales numbers differ slightly due in part to differences in market geography. These differences are within the expected error range.

26 The website https://www.iriworldwide.com, was visited and searched for *"Partially Hydrogenated Oils Products"* on November 16th 2020.

27 We did not simply search for all products that might contain a PHO, because the costs and benefits of any PHO uses covered by the previous declaratory order are attributable to that action, not this rule.

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reformulation and $136,000 for a critical reformulation.[28] Of these 1,180 products, based on discussion with FDA experts, we assume a 50 percent split for both critical and non-critical reformulations. The number of products needing reformulation are multiplied by the average reformulation cost to estimate one-time reformulation costs of about $127 million. ((590*$60,800) + (590*$155,200)) = $127,440,000.

The estimated rule and baseline reformulation costs for each year, and their ~~net~~ present values and annualized values are as presented in Table 8. By baseline costs we are referring to assumed gradual voluntary reformulation costs incurred by food manufacturers operating under the FDA's 2015 declaratory order ~~whereby increased number of consumers will demand healthier food.~~. Meanwhile, with the rule in place, ~~more~~ food manufacturers would be compelled to take action to reformulate their products more quickly than in the absence of regulatory action. In this analysis the costs are assumed to be incurred within a one-year period following the publication date and the ~~compliance~~effective date of the rule. Baseline costs are determined ~~as follows: Each~~by the following assumptions. Based on market trends, we estimate that each year, a certain percentage of the current PHOs are removed from the market. ~~On~~We assume that, on average ~~we assume a~~, each year will see an additional five percent level of PHOs removal~~.~~ relative to the current PHOs, resulting in a linear decrease (see Tables 3-6). Then, that percent of removal costs are assigned to the year. These costs are then

28 As noted above, a major producer of processed foods reported that reformulation cost $25 million for 187 product lines ~~20. R. H. Eckel, S.B., A. H. Lichtenstein and S. Y. Yin Piazza., *Understanding the Complexity of Trans Fatty Acid Reduction in the American Diet*, in *Circulation*. 2007.~~, or an average of $134,000 per product across critical and non-critical reformulations. We assume that these results reflect reformulated products being equally good, in terms of taste, texture and other attributes, as the preceding products with PHOs. As described in a later section of this proposed rule, we anticipate that, ~~if finalized as proposed,~~ post-reformulation products will not be as good as they were previously, which will reduce costs to industry. In other words, if competitors' products are also not using PHOs, then producers do not have to incur as much cost to try to match quality that was achieved with PHO ingredients.

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decreased to account for the fact that removal of PHOs will be less costly in future as technology improves and substitute ingredients become more readily available. While we do not know how much these costs will decrease, our assumptions are based on the past trends where annual ~~decrease~~decreases of between 10 to 30 percent have been observed. In the average case, each year in the future that the baseline costs are incurred reduces the costs by at least 20 percent per year.

Table 8. Reformulation Costs in Millions of 2020 Dollars

Years after Effective Date of Rule (~~from~~ 2023-2042)	Baseline	Rule	Net
1	$6.39	$42.59	$36.20
2	$5.11	$42.59	$37.48
3	$4.09	$42.59	$38.50
4	$3.27	$0.00	-$3.27
5	$2.62	$0.00	-$2.62
6	$2.09	$0.00	-$2.09
7	$1.67	$0.00	-$1.67
8	$1.34	$0.00	-$1.34
9	$1.07	$0.00	-$1.07
10	$0.86	$0.00	-$0.86
11	$0.69	$0.00	-$0.69
12	$0.55	$0.00	-$0.55
13	$0.44	$0.00	-$0.44
14	$0.35	$0.00	-$0.35
15	$0.28	$0.00	-$0.28
16	$0.22	$0.00	-$0.22
17	$0.18	$0.00	-$0.18
18	$0.14	$0.00	-$0.14
19	$0.12	$0.00	-$0.12
20	$0.09	$0.00	-$0.09
	Baseline	Rule	Net
~~Net~~ Present Value 3%	$28.43	$124.10	$95.67
~~Net~~ Present Value 7%	$25.24	$119.60	$94.36
Annualized 3%	$1.91	$8.34	$6.43
Annualized 7%	$2.38	$11.29	$8.91

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2. Relabeling Costs

Based on the database search described above, we estimate that about 1,000 products would have to be relabeled. The average cost of relabeling is about $7,000 per stock-keeping unit (SKU) if the change must be made in one year, according to the FDA relabeling model ~~[Ref. 21].~~[Ref. 30]. Earlier in 2013, we received comments from the industry suggesting that costs could be higher, but we note that this is an average; some firms will face higher costs and others will face lower costs.

We used FDA's labeling cost model that averages the cost of relabeling at $7,000 per ~~stock-keeping unit (~~SKU~~)~~ on condition that such changes would occur within the first year ~~[Ref. 19].~~[Ref. 30]. We inflate this figure to 2020-dollar values and multiply this by 1000 products estimated to need relabeling ($7,340*1,000=$7,340,000). We used Palisades @Risk 7.5 software to run a Monte Carlo simulation to calculate the 90 percent confidence interval for the upper and lower bounds of the expected relabeling costs.[29] This ~~result to~~results in a one-time relabeling cost of about $7.34 million. Table 9 presents the summary of the estimated rule and baseline relabeling costs for each year, their ~~net~~ present values and annualized values are presented. All relabeling costs are assumed to occur in the first year following the date of the rule compliance, whereas under the baseline, the relabeling costs from withdrawing PHO-containing products may continue gradually for up to 13 years according to our estimates given growing consumer awareness and lack of market for these products.

Table 9. Relabeling Costs in Millions of 2020 Dollars

29 For more information on @Risk 7.5 software, see https://www.palisade.com/risk/default.asp

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Years after Effective Date of Rule (from 2023-2042)	Baseline	Rule	Net
1	$0.40	$2.65	$2.25
2	$0.32	$2.65	$2.33
3	$0.25	$2.65	$2.39
4	$0.20	$0.00	-$0.20
5	$0.16	$0.00	-$0.16
6	$0.13	$0.00	-$0.13
7	$0.10	$0.00	-$0.10
8	$0.08	$0.00	-$0.08
9	$0.07	$0.00	-$0.07
10	$0.05	$0.00	-$0.05
11	$0.04	$0.00	-$0.04
12	$0.03	$0.00	-$0.03
13	$0.03	$0.00	-$0.03
14	$0.02	$0.00	-$0.02
15	$0.02	$0.00	-$0.02
16	$0.01	$0.00	-$0.01
17	$0.01	$0.00	-$0.01
18	$0.01	$0.00	-$0.01
19	$0.01	$0.00	-$0.01
20	$0.01	$0.00	-$0.01
	Baseline	Rule	Net
~~Net~~ Present Value 3%	$1.77	$7.71	$5.95
~~Net~~ Present Value 7%	$1.57	$7.43	$5.86
Annualized 3%	$0.12	$0.52	$0.40
Annualized 7%	$0.15	$0.70	$0.55

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3. Retail Bakeries

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~~Many~~Based on industry comments from 2013, many retail bakeries ~~have~~ restricted use of PHOs at little or no cost ~~[Ref. 14].~~[Ref. 28]. However, as noted in a public comment from the National Federation of Independent ~~Business we know that~~Businesses, some retail bakeries will bear costs related to the time to learn new recipes, if they did not limit use of PHOs over the past decade. ~~[Ref. 18].~~[Ref. 29]. We expect that most recipes can be updated at a negligible cost, but that some recipes will

require research or experimentation to adjust to substitute ingredients. We estimate that, on average, several dozen recipes per retail bakery will have to be adjusted. We estimate that at least 3,000 of nearly 9,000 retail bakeries and roughly 3,080 of roughly 661,000 U.S. restaurants according to 2018 data will need to reformulate or substitute ingredients ~~[Ref. 14, 22].~~[Ref. 28].[30] Based on our understanding of the industry, we estimate that it will take the head bakers an average of 200 hours (triangular distribution 0; 200; 400) per bakery, and 20 hours of a restaurant chef (triangular distribution 0; 20; 40) per restaurant. We use U.S. Bureau of Labor Statistics ~~from 2020 of employee compensation valued at $25.00 for the food service sector employee [Ref. 23].~~data from 2020 of employee compensation valued at $25.00 for the food service sector employee.[31] This rate is doubled to account for benefits and overhead, amounting to a total cost of $50 per hour. Therefore: ((3000*200*$50=$30,000,00) + (3080*20*$50=$3,080,000)) giving us a one-time total of roughly $33 million. The discounted costs of the rule's relabeling costs, their baseline for each year and their ~~net~~ present and annualized values are presented in Table 10.

Table 10. Retail Bakery Costs in Millions of 2020 Dollars

Years after Effective Date of Rule (from 2023-2042)	Baseline	Rule	Net
1	$1.63	$10.88	$9.25
2	$1.31	$10.88	$9.58
3	$1.04	$10.88	$9.84
4	$0.84	$0.00	-$0.84
5	$0.67	$0.00	-$0.67
6	$0.53	$0.00	-$0.53

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30 See American Baking Companies at Dun & Bradstreet website: https://www.dnb.com/duns-number.html,website visited on June 17th, 2018.
31 See The U.S Bureau of Labor Statistics. Costs of Employees at http://www.bls.gov/news.release/pdf/ecec.pdf, website visited in March 2021.

7	$0.43	$0.00	-$0.43
8	$0.34	$0.00	-$0.34
9	$0.27	$0.00	-$0.27
10	$0.22	$0.00	-$0.22
11	$0.18	$0.00	-$0.18
12	$0.14	$0.00	-$0.14
13	$0.11	$0.00	-$0.11
14	$0.09	$0.00	-$0.09
15	$0.07	$0.00	-$0.07
16	$0.06	$0.00	-$0.06
17	$0.05	$0.00	-$0.05
18	$0.04	$0.00	-$0.04
19	$0.03	$0.00	-$0.03
20	$0.02	$0.00	-$0.02
	Baseline	**Rule**	**Net**
~~Net~~ Present Value 3%	$7.26	$31.71	$24.44
~~Net~~ Present Value 7%	$6.45	$30.56	$24.11
Annualized 3%	$0.49	$2.13	$1.64
Annualized 7%	$0.61	$2.88	$2.28

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4. Substitute Ingredient Costs

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Substitutes for the PHOs currently used by food producers will likely cost more as a result of this proposed rule ~~[Ref. 24].~~[Ref. 3]. Although the prices for PHOs and their substitutes are currently about the same, it is likely that the expansion in demand for substitutes will cause their price to increase relative to PHOs.

Given the many possible replacement fats and oils, we do not have the data required to properly analyze replacement ingredient costs. However, based on the past market price fluctuations for substitute ingredients such as palm oil, coconut oil and ~~other commodities~~olive oil, we estimate that the price of replacement ingredients could be

between 0 and 20 cents per pound higher than the prices of the PHOs they replace, or an average 25 percent increase ~~[Ref. 25].~~.[32]

The FDA's Environmental Review memo for the ~~2015 declaratory order~~Order shows that about 2.5 billion pounds of PHOs were used in the United States in 2012 ~~[Ref. 26].~~[Ref. 31, 32]. We estimate that the use of PHOs continues to decline significantly, and food products covered by this rule are used in the same proportion that they appear on food labels. This proposed rule is therefore estimated to cover less than 1 percent of the 2.5 billion pounds of PHOs used prior to 2015. At the price of $0.40 per pound the total amount spent on purchasing 12.5 million pounds (0.5%) amount to ($0.43*12,484,167) = $5.37 million. ~~Given that the longer compliance timeline allows more time for research to find new and better ingredients, we~~We assume that the costs of replacement will continue to decline over time due to improving technologies and investment in research to find better ingredients. To that effect, we assume that the cost of finding alternative ingredients will level out over time at about 25~~%~~ percent of the nearly $5.4 million of the prior to 2015 annual spending on PHOs ($5,~~356,308~~440,000 * 0.25=$1,~~339,079~~360,000). The average annual cost of replacing these PHOs is therefore about $1.~~34~~36 million. The baseline is a gradual 20-year removal of PHOs, meaning that baseline costs slowly increase to the full amount. The estimated rule and baseline substitute ingredient costs for each year, and their ~~net~~ present values and annualized values are presented in Table 11.

32 See Palm Oil Monthly price commodities as visited and cited in May 2019 at https://www.indexmundi.com/commodities/?commodity=palm-oil&months=120.https.

Table 11. Substitute Ingredient Costs in Millions of 2020 Dollars

Years after Effective Date of Rule (from 2023-2042)	Baseline	Rule	Net
1	$0.00	$1.31	$1.31
2	$0.07	$1.~~31~~28	$1.~~25~~22
3	$0.13	$1.~~31~~26	$1.~~18~~13
4	$0.20	$1.~~31~~23	$1.~~11~~04
5	$0.26	$1.~~31~~21	$~~1.05~~0.94
6	$0.33	$1.~~31~~18	$0.~~98~~85
7	$0.39	$1.~~31~~15	$0.~~92~~76
8	$0.46	$1.~~31~~13	$0.~~85~~67
9	$0.52	$1.~~31~~10	$0.~~79~~58
10	$0.59	$1.~~31~~07	$0.~~72~~49
11	$0.66	$1.~~31~~05	$0.~~66~~39
12	$0.72	$1.~~31~~02	$0.~~59~~30
13	$0.79	$1.~~31~~00	$0.~~52~~21
14	$0.85	$~~1.31~~0.97	$0.~~46~~12
15	$0.92	$~~1.31~~0.94	$0.~~39~~03
16	$0.98	$~~1.31~~0.92	~~$.~~$0.~~33~~07
17	$1.05	$~~1.31~~0.89	~~$.~~$0.~~26~~16
18	$1.11	$~~1.31~~0.87	~~$.~~$0.~~20~~25
19	$1.18	$~~1.31~~0.84	~~$.~~$0.~~13~~34
20	$1.25	$~~1.31~~0.81	~~$.~~$0.~~07~~43
	Baseline	**Rule**	**Net**
~~Net~~ Present Value 3%	$8.56	$~~20.09~~16.66	$~~11.53~~8.10
~~Net~~ Present Value 7%	$5.44	$~~14.86~~12.68	$~~9.42~~7.25
Annualized 3%	$0.58	$1.~~35~~12	$0.~~77~~54
Annualized 7%	$0.51	$1.~~40~~20	$0.~~89~~68

5. Costs ~~of~~to Producers due to Changed Product Properties

Although most previous reformulations resulted in products that had similar taste, texture, mouth feel, and shelf life, it is ~~likely~~possible that some reformulations required by this ~~proposed~~ rule, if finalized, will result in products that do not have similar properties. As described in the books "Emulsifiers in Food Technology", and "Trans Fats Alternatives" PHOs have many characteristics that cannot be perfectly duplicated ~~[Ref. 27, 28].~~[Ref. 33, 34]. Replacing PHOs in some products could lead to changes in these

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functional and organoleptic properties that ~~reduce the amount consumers are willing to pay for those products~~may increase producers' cost.

~~In the categories of dry grocery, dairy, and frozen foods, total annual sales prior to 2015 declaratory order were about $150 billion according to Nielsen scanner data. Since less than 1 percent of packaged food products are covered by this proposed rule, we estimate that the amount spent on these foods has declined substantially since the 2015 declaratory order to less than $1 billion [Ref. 16, 17]. Based on the observed cross-price elasticities of demand for oils used in food production and the submitted public comments describing the product property changes due to reformulation, we assume that FDA's requirement to reformulate products ingredients to remove PHOs will result in the loss of less than one percent of the total value of these foods (triangular distribution 0%, 1%, 2%) [Ref. 14, 29]. This assumption is based on industry's experience with previous reformulations which resulted in products with comparable consumer acceptance and shelf life[Ref. 30]. The percent of products with less consumer acceptance or shelf-life was extremely low. This loss in value may be borne by the producer or the consumer. Given that the amount of food containing PHO ingredients consumed in the U.S. is less than 3 percent, we assume that both consumer and producer surplus resulting from these reformulations would be very small. For lack of data, we are unable to quantify the surplus or loss to both consumers and producers.~~

~~We specifically ask for comment on this assumption.~~

~~A one percent loss of value~~In the categories of dry grocery, dairy, and frozen foods, total annual sales prior to Order were about $150 billion according to Nielsen

scanner data. Since less than 1 percent of packaged food products are covered by this proposed rule, we estimate that the amount spent on these foods has declined substantially since the Order to less than $1 billion.[33] Based on literature and recent industry comments on some of FDA's regulations, we assume that the requirement to reformulate product ingredients to remove PHOs will result in a small increase in producer's cost and consequently dampen producer profits [Ref. 24, 27, 28, 35]. The reduction in producer profits could be due to food manufacturers' learning experience with new recipe development or shorter shelf-life compared to use of PHO containing recipes [Ref. 36].

The amount of food containing PHO ingredients consumed in the U.S is currently less than 3 percent. Studies have also shown the cross-price elasticities of demand for oils used in food production to be very small [Ref. 37]. For lack of better information, we are unable to comprehensively quantify these changes.

A 1 percent loss of value for producers would cause a loss of $~~8~~7.85 million each year or a total ~~net~~ present value of $~~125~~89.04 million over 20-year period.[34] The baseline is a gradual 20-year removal of PHOs, meaning that annual costs of changed product properties slowly increase to the full amount. The estimated rule and baseline costs of changed product properties for each year, and their ~~net~~ present values and annualized values are presented in Table 12.

Table 12: Cost to Producers of Changed Characteristics in Millions of 2020 Dollars

33 See market scanner data at https://app.labelinsight.com and https://iriworldwide.com.
34 We request comment on whether the 1-percent assumption could be refined using, for example, the producer-relevant estimates developed by Bauner et al. [Ref. 27].

Years after Effective Date of Rule (from 2023-2042)	**Baseline**	**Rule**	**Net**
1	$0.00	$~~8.17~~7.85	$~~8.17~~7.85
2	$0.~~41~~39	$~~8.17~~7.85	$7.~~76~~46
3	$0.~~82~~79	$~~8.17~~7.85	$7.~~35~~07
4	$1.~~22~~18	$~~8.17~~7.85	$6.~~94~~68
5	$1.~~63~~57	$~~8.17~~7.85	$6.~~53~~28
6	$~~2.04~~1.96	$~~8.17~~7.85	$~~6.12~~5.89
7	$2.~~45~~36	$~~8.17~~7.85	$5.~~72~~50
8	$2.~~86~~75	$~~8.17~~7.85	$5.~~31~~11
9	$3.~~27~~14	$~~8.17~~7.85	$4.~~90~~71
10	$3.~~67~~53	$~~8.17~~7.85	$4.~~49~~32
11	$~~4.08~~3.93	$~~8.17~~7.85	$~~4.08~~3.93
12	$4.~~49~~32	$~~8.17~~7.85	$3.~~67~~53
13	$4.~~90~~71	$~~8.17~~7.85	$3.~~27~~14
14	$5.~~31~~11	$~~8.17~~7.85	$2.~~86~~75
15	$5.~~72~~50	$~~8.17~~7.85	$2.~~45~~36
16	$~~6.12~~5.89	$~~8.17~~7.85	$~~2.04~~1.96
17	$6.~~53~~28	$~~8.17~~7.85	$1.~~63~~57
18	$6.~~94~~68	$~~8.17~~7.85	$1.~~22~~18
19	$7.~~35~~07	$~~8.17~~7.85	$0.~~82~~79
20	$7.~~76~~46	$~~8.17~~7.85	$0.~~41~~39
	Baseline	Rule	Net
~~Net~~ Present Value 3%	$~~53.32~~51.29	$~~125.13~~120.37	$~~71.81~~69.07
~~Net~~ Present Value 7%	$~~33.86~~32.57	$~~92.57~~89.04	$~~58.70~~56.47
Annualized 3%	$3.~~58~~45	$8.~~41~~09	$4.~~83~~64
Annualized 7%	$3.~~20~~07	$8.~~74~~40	$5.~~54~~33

6. Costs of Reading the Rule

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Individuals from affected entities will need to devote time to reading and understanding this rule. We assume an average of one food service ~~sector employee~~manager for each entity affected by this rule will take time to read and understand the requirements of this rule. At an adult average reading speed of 200-250 words per minute, we estimate that each reader will spend about an hour. We value the opportunity cost of one hour using the Bureau of Labor Statistics (BLS) mean hourly wage of food service ~~employee,~~manager ($29.33), which is doubled to account for

benefits and overhead. We estimate the time spent learning about the rule at a cost of $~~50 per entity (BLS 2020) [Ref. 23].~~58.66 per entity (BLS 2020).[35] Multiplying this estimate by the total number of restaurants (#3080) and retail bakeries (#3000) affected by this rule yields a one-time total of $~~300,000~~356,653.

7. Total Costs

Total costs are presented in Table 13. The total ~~net~~ present value costs are $~~308.74~~300.55 million at a 3 percent rate and $~~265.02~~259.31 million at a 7 percent rate. These estimate costs are $~~25.02~~24.48 million when annualized at a ~~seven~~7 percent discount rate and $20.~~75~~20 million annualized at a ~~three~~3 percent discount rate.

Table 13. ~~Net~~ Present Value Costs over 20 Years in Millions of 2020 Dollars

Cost Category	3 percent	7 percent
1. Reformulation Costs	$~~—~~124.10	$~~-~~119.60
2. Relabeling Costs	$~~——~~7.71	$~~——~~7.43
3. Retail Bakery Costs	$~~——~~31.71	$~~—~~30.56
4. Substitute Ingredient Costs	$~~——20.09~~16.66	$~~—14.86~~12.68
5. Costs of Changed Product Properties	$ ~~125.13~~120.37	$ ~~92.57~~89.04
Total Net Present Value Costs	**$ ~~308.74~~300.55**	**$ ~~265.02~~ 259.31**
Total Annualized Costs	**$ ~~——~~20.~~75~~20**	**$ ~~25.02~~24.48**

G. Distributional Effects

~~-~~Studies have shown that while mean population intakes of TFA typically average between 2 – 4% of energy, a substantial minority of the underserved population can have much higher intakes. Specifically, young adults, adolescents and low-income populations

35 The U.S. Bureau of Labor Statistics, Employers Cost of Employees -2020, accessed on January 14th, 2021, at http://www.bls.gov/news.release/pdf/ecec.pdf.

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tend to have higher intakes of processed foods containing high quantities of trans fat. Because foods that contain partially hydrogenated oils high in trans-fat are inexpensive, they are more economical for lower-income consumers. Low-income consumers may also have limited access to fresh foods, making it more difficult to make healthier food choices ~~[Ref. 31]~~[Ref. 38]. ~~PHOs~~ PHO-containing food products tend to have ~~some~~ commercial advantages over many unhydrogenated oils, such as longer shelf-life, solidity at room temperature and greater stability during high temperature commercial deep-frying. Low-income populations therefore prefer these cheaper options to save money and for their longer ~~-~~shelf-life ~~[Ref. 32].~~[Ref. 39].

According to National Health and Nutrition Examination Survey (NHANES) 2007-2012, almost 60% of calories consumed in the US came from ultra-processed foods. The consumption of these foods decreased with age and income level and was higher for non-Hispanic whites or non-Hispanic blacks than for other race/ethnicity groups. Consumption of highly processed foods with TFAs was also lower for people with college degrees than ~~for~~those with lower levels of education ~~[Ref. 31]~~[Ref. 38]. Most of the foods consumed were frozen/shelf-stable meals, canned meat or fish, baked goods like donuts, breads, cakes, cookies, and pies. Most of these foods are known to use PHO~~-~~containing ingredients. Based on these studies, we can infer that the large portion of benefits and costs realized from implementing this rule will ~~go to~~be experienced by low-income groups and those without college degrees who according to these studies are known to constitute the largest market for PHO~~-~~containing foods. This rule may therefore have direct positive health benefits to these underserved populations~~.~~ ~~Consumers of products affected by this rule may experience some form of wealth~~

~~transfers through higher prices of their preferred goods. However, it is also possible that these consumers could experience a gain in consumer surplus if substitute products become cheaper, healthier and with better taste.~~ while at the same time generating higher prices of their preferred goods.

H. International Effects

We expect that this action will increase imports of ingredient substitutes, as domestically produced PHOs are replaced in part by foreign-produced palm oil. As described above, about 125 million pounds of these prior-sanctioned uses of PHOs are used each year, and we expect that about 30% of this will be replaced with imported palm oil, coconut oil, or olive oil at a cost of about 50 cents a pound. Therefore, we expect that this action will be responsible for a $18.7 million annual increase in imports. (125 * 30% * $0.5=$18.7).

I. Uncertainty and Sensitivity Analysis

In this section, we present the uncertainty analysis used to generate the bottom-line confidence intervals for net benefits.

Monte Carlo Simulation

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

1. Randomly determine the annual baseline for PHO reduction associated with this proposed rule without FDA action (triangular distribution 0, 5%, 10%). The reduction is a percentage of current usage each year, generating a linear decrease.

2. Draw a random number from all distributions used as inputs to estimate costs and recalculate the cost of the action.

3. Repeatedly ~~chose~~choose each one of the four methods in the risk assessment.

4. For the chosen method, draw the health gains from the distribution provided.

5. Choose a QALY value to use from the specified distribution.

6. Calculate benefits using the chosen variables and subtract the costs.

The results of the 100,000-simulation run, rounded to two significant figures, are shown as Table 1 in the Executive Summary.

The range of benefit estimates is primarily driven by the different results of the different methods, the standard deviation of health effects generated by each method, and uncertainty about the rate of baseline removal on PHOs.

J. Analysis of Regulatory Alternatives to the Proposed Rule

Solely for the purpose of this economic analysis, we have identified three regulatory alternatives to the proposed rule as described below. These options may or may not be legally viable, but we present the economic consequences of them:

1. Inform consumers that some products still contain PHOs and recommend that they read labels to choose what to consume.

2. Institute a product standard, i.e., limit the amount of *trans* fat that a product may contain.

3. Delay the compliance date by an additional two years.

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1. Consumer Label Reading

One regulatory alternative would be to take no action to amend our regulations and undertake a public messaging campaign to inform the at-risk population that some products still contain PHOs and recommend that they read labels to choose what to consume. ~~There are about 155 million Americans over the age of 40, and over 60% of them have one or more major risk factors for CHD [Ref. 33, 34]. If only 20% of these at-risk population are currently reading labels to avoid PHO-containing food products, a public health campaign could further improve label reading from say 20% to 60%. This would bring the total number of at-risk populations reading labels to about 56 million people. There will still be about 37 million at-risk Americans who wouldn't be reading labels to avoid PHO-containing food products.~~There are roughly 250 million Americans over the age of 18 years. According to CDC and the American Heart Association (AHA) the risk and prevalence of cardiovascular disease increases with age and those above the age of 50 years are the most at risk. AHA estimates that only 0.9 percent to adults aged 18-44 years have cardiovascular disease, 5.9 percent of those aged 45-64 years and 18.2 percent of individuals aged 65 years and above 36 [Ref. 40, 41].

We apply these risk proportions to the total population to yield an at-risk population total of 16.28 million. Based on these numbers, if only 20 percent of these at-risk population (3.25 million) are currently reading labels to avoid PHO-containing food products, a public health campaign could further improve label reading to above the 20 percent level. For example, improving the reading level to 60 percent would result in 9.77

36 The U.S. Census Bureau, Age and Sex Composition in the United States: 2019 at. https://www.census.gov/data/tables/2019/demo/age-and-sex/2019-age-sex-composition.html

million of at-risk individuals reading labels. However, there will still be 6.51 million at-risk Americans who would not read labels.

If consumers read labels to look for PHOs, we estimate that this would take about one minute a week per label-reader. This means that the at-risk population reading labels because of the FDA awareness influence campaign will be ~~37 million or roughly 40~~9.77 million people resulting ~~to~~in nearly ~~40 million~~163,000 hours of reading these labels per year.

We ~~adopt an~~construct a range where the upper bound is the full loaded mean hourly wage and the lower bound is the hourly value of time based on after-tax ~~wages~~wage to ~~quantify the opportunity cost of changes in~~ value time ~~use~~ for unpaid activities. ~~This approach matches the default assumptions for valuing changes in time use for individuals undertaking administrative and other tasks on their own time, which are outlined in an ASPE report on "Valuing Time in U.S. Department of Health~~For the upper bound estimate, we take the mean hourly wage in 2020 of $27.07 and ~~Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices."[37] We~~double it to generate a fully loaded wage of $54.14.[38] To generate the lower bound, we start with a measurement of the usual weekly earnings of wage and salary workers of $998.[39] We divide this weekly rate by 40 hours to calculate an hourly pre-tax wage rate of $24.95. We adjust this hourly rate downwards by an estimate of the effective tax rate for median

~~37 U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation. 2017. "Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices." https://aspe.hhs.gov/reports/valuing-time-us-department-health-human-services-regulatory-impact-analyses-conceptual-framework.~~

38.More information is available at The U.S. Bureau of Labor Statistics website.

39 U.S. Bureau of Labor Statistics. Employed full time: Median usual weekly nominal earnings (second quartile): Wage and salary workers: 16 years and over [LEU0252881500A], retrieved from FRED, Federal Reserve Bank of St. Louis; https://fred.stlouisfed.org/series/LEU0252881500A, June 9, 2022. Annual Estimate, 2021.

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income households of about 17~~%,~~ percent, resulting in a post-tax hourly wage rate of $20.71. ~~We adopt this as our estimate~~We use the full loaded wage upper and national mean wage lower bound to also generate an average wage of ~~the hourly value of time for~~$37.43. We use these wage estimates to quantify the opportunity cost of changes in time use for unpaid activities.[40]

~~When valued at the year 2020 average hourly compensation of $20.71, the total cost of at-risk consumers reading labels will be over $770.4 million per year [Ref. 23]. These costs are much higher than the costs of reformulation described above.~~

For the 9.77 million at-risk consumers reading labels, the mean cost of reading labels would be $6.1 million per year (=163,000 hours x $37.43), with a lower bound of $3.3 million (=163,000 hours x $20.71) and an upper bound of $8.8 million (=163,000 hours x $54.14). These costs are lower than present value costs of reformulation reported above.

We note that this option may ~~not be desirable since it is~~be unlikely to achieve 100 percent protection of the population at- risk from consuming PHO-containing food products. Reading labels may not necessarily change their decisions not to purchase PHO-containing products but complete absence of PHO trans-fats would achieve this goal. It is also important to note that not all consumers may care to read product labels for various reasons. The risks of not reading labels for at-risk consumers may result in expensive and adverse health consequences for consuming foods containing PHOs. As

40 U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation. 2017. "Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices." https://aspe.hhs.gov/reports/valuing-time-us-department-health-human-services-regulatory-impact-analyses-conceptual-framework.

explained in the ~~declaratory order~~Order, PHOs are no longer GRAS. These existing regulations, which include PHOs in standards of identity and affirm certain uses of PHOs as GRAS, ~~must~~are therefore ~~be~~being amended to reflect current scientific knowledge. In addition, we propose to revoke all prior-sanctioned uses of PHOs to protect the public from consuming harmful substances.

2. Product Standard

According to the Grocery Manufacturers Association (GMA~~),~~) feedback in 2014, the 2003 FDA's amendment of its regulations on nutrition labeling, requiring trans-fat contents to be declared on the nutrition label of conventional foods and dietary supplements resulted ~~to industry's voluntary reformulation to reduce trans-fats contents in their products [Ref. 5].~~in industry's voluntary reformulation to reduce *trans*-fat contents in their products [Ref. 11]. GMA has therefore argued that FDA institute product standards limiting the industrially produced *trans*-fat content of a product. ~~We evaluate such an alternative regulatory approach and hereby present our findings.~~ From our review of market scan data, there were a total of 1,180 products that required product reformulation. Based on input from FDA subject matter experts, we assume that 50 percent would require critical reformulation and the remaining 50 percent would not require critical reformulation. We estimate that a product standard would result in fewer product reformulations and may eliminate the need for about 590 (1,180 x 50 percent) noncritical reformulations. Solely for the purposes of this alternative analysis, we estimate that a product standard ~~would remove~~may exempt 90 percent of the PHOs that the rule would remove.

Fewer reformulations would give a one-time savings of roughly $60 million, relative to the proposed rule. Substitute ingredient costs would decrease by 10 percent, for a ~~net~~ present value (~~NPV~~PV) savings of $9 million. The cost of changed product characteristics would likely be reduced by half, for an ~~NPV~~PV savings of $40 million. The total ~~NPV~~PV of cost savings from the product standard alternative is then $93 million, relative to the proposed rule.

Given the assumption that most PHO consumption comes from the 590 products requiring a critical reformulation, a product standard would ~~remove~~exempt 90 percent of the PHOs that this proposed rule would remove and ~~would achieve~~ 90 percent of the health benefits~~.~~ would not be realized. The ~~NPV~~7 percent PV of health benefits is $~~2.4 billion~~652 million. A product standard could then cause $~~550~~587 million of health harm, relative to the proposed rule.

We note that this is also not a viable option~~. It is necessary to amend our regulations to conform them to the current state of scientific knowledge regarding PHOs. As explained in the declaratory order~~.. As explained in the Order, PHOs are no longer GRAS for any use in human food, and a threshold below which PHOs may be safely used in the food supply has not been identified based on the available science. These existing regulations, including regulations affirming certain uses of PHOs as GRAS, ~~must~~are therefore ~~be~~being amended to reflect current scientific knowledge.

3. Delayed Compliance

~~A compliance~~An effective date three years after publication rather than 135 days after publication would make reformulation cheaper and save two years of rule costs. The

total (7% ~~NPV~~PV) costs of the rule would drop ~~to $247~~from $263 million~~, from $265~~ to $245 million, for ~~an NPV~~a PV saving of $18 million relative to the proposed rule.

The delayed compliance date would cost two years of health benefits. Total net present value (7% NPV) benefits would fall to $~~1.87 billion~~529 million, from $~~2.18 billion~~652 million, resulting in foregone benefits of almost $~~309.37~~123 million because of more people suffering from CHD following consumption of PHO-containing foods.

III. ~~Initial~~ Small Entity Analysis

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this proposed rule may require some small business entities to undertake costly reformulations, we find that the proposed rule will have a significant economic impact on a substantial number of small entities. This analysis, as well as other sections in this document, serves as the Initial Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

A. Description and Number of Affected Small Entities

As described above, this proposed rule ~~will~~would require about 1,200 food products to be reformulated. We reviewed the list of products likely to be affected ~~[Ref. 16, 17].~~[41] In addition to these products, the rule could affect roughly up to 6,000 small retail bakeries and restaurants. Most large food manufacturers already ceased the use of PHO containing products, ingredients~~,~~ and food formulations after FDA's ~~2015 declaratory order~~Order revoking PHOs' GRAS status. Our review of PHO-containing

41 See these websites: https://www.labelinsight.com and https://www.iriworldwide.com.

products did not find any large nationally marketed products, an indication that most entities continuing to use PHOs ingredients in their food products are likely very small firms with small pools of clienteles and sales volumes. We therefore expect this proposed rule to affect up to 95% of small size manufacturing firms required to use alternative ingredients or tweak their product formulations to avoid the use of PHOs. The business entities affected by this rule are however, expected to spend less on reformulating their products as we anticipate increased availability of alternative ingredients in the market. In the last six years since the declaratory order was issued, there have been more discoveries of new ingredients and formulations to replace PHOs ~~[Ref. 35, 36]~~[Ref. 42, 43]. Because of their increased availability and existence of new technologies enabling mass productions, these alternatives will continue to get cheaper as compared to the pre-2015 period.

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

As described earlier, the average annualized cost of this proposed ~~rule~~ule to food manufacturers per affected product, including reformulation, relabeling, expected replacement ingredient costs, and product characteristic changes, will be less than $3,500. This is calculated from the seven percent annualized costs of the rule of $25.02 million divided by estimated total products requiring reformulation and total bakery and restaurants that will be required to change their food or baking recipes (($25,020,000/ (1,200 + 3,000 + 3100)) = $3,427. These are the cost numbers found using a seven percent discount rate, which is closer to the borrowing costs of small entities. It is unlikely that most small entities will have any products needing reformulation given the length of time it has taken for FDA to follow up on the 2015 declaratory order with this

proposed rule. According to Dun & Bradstreet data, the average annual sales of food manufacturing companies with less than 500 employees are about $14 million ~~[Ref. 22].~~[42] We do not know what percentage of these costs will be passed on to consumers in the form of higher food prices, but even when costs are passed on to consumers, small entities will likely end up paying a small portion of their costs up-front before such costs can be recovered in later years, which could impact their cash flow and short-term profitability. Depending on market conditions, it is also possible that some small businesses will choose to stop producing their affected foods, rather than paying the costs of this proposed rule.

As described above, a significant number of retail bakeries and restaurants could face a one-time cost to reformulate their products. The average annualized cost per retail bakery/restaurants of this reformulation is estimated at about $500 (i.e. ~~($~~ $2,880,000/6000 = $480) of labor costs.

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. We also examine the costs and benefits of establishing a delayed compliance date for small businesses as compared to other businesses.

Since most entities affected by this rule are small businesses, we explore a scenario where about 10~~%~~ percent of these entities will be very small businesses of less

42 See Dun & Bradstreet at https://www.dnb.com/duns-number.html.

than 5 employees. An exemption for these very small businesses would reduce annualized costs to each small production business by roughly $300 per reformulated product it sells. Annualized costs to all small businesses combined would be reduced by roughly about $2.3 million. Additionally, should all 3,000 retail bakeries be exempt, the annualized costs would be reduced by an additional $9.3 million. However, a permanent exemption would also see reduced health benefits from the rule by some percentage, based on the number of people who will continue to consume foods containing PHOs from exempted small businesses. Based on industry sales data *Comment FDA-2013-N-1317-0172*, we estimate that each product from a small business is consumed by about 10 percent of the people who consume the typical product from a large business ~~[Ref. 5, 14].~~[Ref. 11, 28]. Because 10 percent of the products are from very small entities, the consumption of products from small entities is about 1 percent of the total, meaning that exempting small business from the proposed rule would reduce annualized health benefits by 1 percent, or $~~22~~0.62 million ($~~2.24 billion~~61.5 million * 1% = $~~22~~0.62 million).

A delayed compliance date that allowed two additional years for small businesses to comply would relieve small entities of the first two years of increased ingredient costs and product property costs, and as described above, we expect reformulation costs to fall by an average of 20 percent per year. We estimate that a two-year delayed compliance date would reduce the average annualized cost of this proposed rule to each small manufacturing business by roughly $700 per reformulated product it sells ($3,427 per product * 0.2 = $685.40). We estimate that annualized costs to retail bakeries would fall by about 50 percent due to the delayed reformulation. Annualized costs to all businesses

entities combined would further be reduced by about $4.1 million. As described above, a delayed compliance date would cause the benefits of the rule to be reduced by 1 percent, for the first two years. We estimate that this would reduce annualized health benefits by about $220.62 million.

~~V~~

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