

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Use of Salt Substitutes to Reduce the Sodium Content in Standardized Foods

Docket No. FDA-2022-N-2226

Final Regulatory Impact Analysis
Final Regulatory Flexibility Analysis
Unfunded Mandates Reform Act Analysis

Economics Staff
Office of Economics and Analysis
Office of Policy, Legislation, and International Affairs
Office of the Commissioner

Executive Summary

The final rule amends the Food and Drug Administration's (FDA's) definitions and standards of identity (SOI; the acronym is used to refer to both the singular "standard of identity" and the plural "standards of identity") that specify salt (sodium chloride) as a required or optional ingredient to permit the use of safe and suitable salt substitutes to replace some or all of the salt used in the manufacturing of standardized foods. We qualitatively discuss the benefits of the final rule, which come in the form of increased flexibility for manufacturers. We qualitatively discuss the costs of the final rule, which only occur if the manufacturer chooses to voluntarily make a salt substitution.

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I. Introduction and Summary

A. Introduction

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, Executive Order 14192, the Regulatory Flexibility Act (5 U.S.C. 601-612), the Congressional Review Act/Small Business Regulatory Enforcement Fairness Act (5 U.S.C. 801, Pub. L. 104-121), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4).

Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits. Rules are significant regulatory actions under section 3(f)(1) of Executive Order 12866 if they may have an annual effect on the economy of \$100 million or more; 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, or tribal governments or communities. The Office of Information and Regulatory Affairs (OIRA) has determined that this final rule is a significant regulatory action as defined by section 3(f)(1) of Executive Order 12866.

Executive Order 14192 requires that any new incremental costs associated with certain significant regulatory actions “shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least 10 prior regulations.” The final rule allows manufacturers of affected products to gain flexibility in using salt substitutes. This flexibility potentially would allow them to reformulate their products to increase their product offerings and therefore potentially increase their profits. Producing new products can reduce average operational costs by enabling economies of scale and scope. Increasing the number of products increases consumer surplus by providing more options tailored to individual preferences, allowing consumers to choose products that better align with their willingness to pay. However, due to the voluntary nature of the rule, no changes in costs of production or increase in consumer satisfaction can be quantified. This final rule is considered an Executive Order 14192 deregulatory action.

Because this rule is likely to result in an annual effect on the economy of \$100 million or more or to meet other criteria specified in the Congressional Review Act/Small Business Regulatory Enforcement Fairness Act, OIRA has determined that this rule does fall within the scope of 5 U.S.C. 804(2).

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

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes estimates of anticipated impacts, before issuing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation)

in any one year.” The current threshold after adjustment for inflation is \$187 million, using the most current (2024) Implicit Price Deflator for the Gross Domestic Product. This final rule will not result in a mandated expenditure in any year that meets or exceeds this amount.

B. Overview of Benefits, Costs, and Transfers

The final rule amends the Food and Drug Administration’s (FDA’s) definitions and standards of identity (SOI; the acronym is used to refer to both the singular “standard of identity” and the plural “standards of identity”) that specify salt (sodium chloride) as a required or optional ingredient to permit the use of safe and suitable ingredients to replace some or all of the salt used in the manufacturing of standardized foods. There are no regulatory costs as there are no regulatory requirements or regulatory penalties if manufacturers of a standardized food choose not to take advantage of the flexibility to use salt substitutes. Other costs considered may come from voluntary reformulation and re-labeling costs, as well as potential consumer dissatisfaction with altered product properties. The benefits of the final rule come in the form of increased flexibility for manufacturers and potential public health benefits stemming from decreased sodium consumption. We believe that some manufacturers may reformulate (and as a result, re-label) standardized foods with salt substitutes to lower sodium in their products if the voluntary reformulation of their products would be profitable (producer surplus). The resulting new products may lead to increased consumer satisfaction (consumer surplus). Table 1 summarizes the estimated benefits and costs of the final rule.

Table 1. Summary of Benefits, Costs, and Distributional Effects of the Final Rule (millions of 2024 dollars)

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized \$millions/ year	\$0	\$0	\$0	2024	7%	10 years	
		\$0	\$0	\$0	2024	3%	10 years	
	Annualized Quantified							
	Qualitative	Potential increased consumer surplus and producer surplus. Potential health benefits of reduced sodium consumption.						
Costs	Annualized Monetized \$millions/ year	\$0	\$0	\$0	2024	7%	10 years	
		\$0	\$0	\$0	2024	3%	10 years	
	Annualized Quantified							
	Qualitative	Compliance with the final rule is voluntary. There are no regulatory costs. Potential costs from voluntary reformulation and re-labeling, as well as possible consumer dissatisfaction.						
Transfers	Federal Annualized Monetized \$millions/ year	\$0	\$0	\$0	2024	7%		
		\$0	\$0	\$0	2024	3%		
	From/To	From:			To:			
	Other Annualized Monetized \$millions/ year	\$0	\$0	\$0	2024	7%		
		\$0	\$0	\$0	2024	3%		
	From/To	From:			To:			
Effects	State, Local or Tribal Government: Small Business: Wages: Growth:							

In line with Executive Order 14192, in Table 2 we estimate present and annualized values of costs, cost savings, and net costs over a perpetual time horizon. We estimate that this rule will generate \$0 in annualized net costs at a 7 percent discount rate, discounted relative to year 2024, over a perpetual time horizon.

Table 2. Executive Order 14192 Summary Table (millions of 2024 dollars, discounted over a perpetual time horizon relative to year 2024 at a 7 percent discount rate)

	Primary Estimate	Low Estimate	High Estimate
Present Value of Costs	\$0	\$0	\$0
Present Value of Cost Savings	\$0	\$0	\$0
Present Value of Net Costs	\$0	\$0	\$0
Annualized Costs	\$0	\$0	\$0
Annualized Cost Savings	\$0	\$0	\$0
Annualized Net Costs	\$0	\$0	\$0

C. Comments on Preliminary Economic Analysis of Impacts and Our Responses

(Comment 1) Some comments indicate that the efficacy of the final rule should be evaluated following its implementation.

(Response 1) As required by Executive Orders 12866 and 13563, FDA periodically reviews existing significant regulations to determine whether they should be modified, expanded, or repealed to ensure that regulations are more effective and less burdensome in achieving their objectives. After enough time has passed after the implementation of the final rule, FDA will consider conducting a retrospective study of the final rule to determine its efficacy.

(Comment 2) Some comments say FDA should require labels indicating a product uses salt substitutes to reduce sodium intake because economic research and theory find that consumers often lack full information in making decisions. The comments assert that by informing consumers that a product is “low sodium” or includes salt substitutes, consumers may be more likely to choose the lower sodium product, thus improving health outcomes. Some comments state manufacturers would not change food products without market incentives and that consumer preferences for lower sodium foods will encourage change.

(Response 2) As discussed in the preamble, the final rule does not prescribe any new labeling requirements for ingredients used to replace salt in standardized foods; existing labeling requirements apply to salt substitutes used in standardized foods. Ingredients, including salt substitutes, are required to be declared in the ingredient statement of standardized foods by their common or usual names (§ 101.4(a)(1); see also 21 U.S.C. 343(i)(2) and § 130.3(e)). Our regulations, at § 101.4(b), require that food ingredients be declared by a specific name and not a collective (generic) name unless a specific exception is provided. Additionally, the Nutrition Facts label, including nutrient declaration and percent Daily Value, is available to provide quantitative information for consumers to use. For food labeled as “low sodium,” the sodium content of the food must meet the requirements of the nutrient content claim (21 CFR 101.61(b)(4)).

We do not require any additional labeling of new ingredients used in reformulated standardized or non-standardized foods. However, manufacturers of both standardized and non-standardized foods

can choose to disclose information on the package voluntarily. For example, manufacturers could include reformulation information if statements made on the package are truthful and not misleading (see section 403(a)(1) of the FD&C Act (a food is deemed to be misbranded if its labeling is false or misleading in any particular)).

(Comment 3) Some comments note that the preliminary regulatory impact analysis stated that there are no regulatory costs if manufacturers voluntarily use salt substitutes in their products but raise concerns about potential increases in costs for reformulated standardized foods. The comments assert that the price of salt substitutes can range between 1.1 to 14.6 times that of regular salt. The comments state further that higher prices could render these foods unaffordable for consumers and push them to purchase cheaper foods with more sodium chloride, which essentially defeats the overall goal of the rule, which is to improve consumer dietary patterns by reducing sodium intake. The comments conclude that regulations must also focus on making healthier food choices more accessible and affordable for consumers by making a comparable price point to the foods without salt substitutes.

Other comments say that product reformulation takes time and money and that the flexibility to use salt substitutes would help keep reformulation costs down.

(Response 3) The preliminary regulatory impact analysis estimated that there are no regulatory costs to manufacturers as there are no regulatory requirements or regulatory penalties relative to the baseline of taking no regulatory actions. It is possible that a voluntary action by a manufacturer could generate costs to the manufacturer; however, we are unable to estimate any potential voluntary industry costs, and similarly are unable to estimate any potential impacts on consumer prices.

While we recognize that salt substitutes are generally more expensive than salt, the price differential alone is unlikely to be the determining factor in a manufacturer's reformulation decision. We agree that providing ingredient flexibility to use salt substitutes will help manufacturers minimize voluntary costs of reformulation.

(Comment 4) In the proposed rule, we requested comment regarding inclusion of regulatory alternatives allowing the use of only specified salt substitutes, at only specified levels of substitution, for only specified purposes, for only specified products, in conjunction with only specified ancillary formulation changes, or with specified labeling requirements. In response to the request, some comments recommend against adopting the regulatory alternatives to the proposed rule.

(Response 4) We are finalizing the rule as proposed to allow for greater flexibility to adopt salt substitutes, thereby maximizing the potential for reduced sodium consumption by the public. In Section II.I, we analyze regulatory alternatives to the final rule.

(Comment 5) Some comments note that FDA only appears to be focused on potential healthcare costs associated with sodium consumption and does not suggest any guidelines to mitigate the potential health risks of consuming the salt substitute, potassium chloride. These comments urge

FDA to recognize people who must limit potassium intake and consider how to lessen any potential risks to them. Some comments say the rule would increase costs of patient counseling for those with chronic kidney disease. Other comments said that the rule would result in healthcare savings, including Medicare and Medicaid.

(Response 5) FDA recognizes that some consumers may need to limit their potassium intake. We expect that the Nutrition Facts label and ingredient statement will provide sufficient information for these consumers to make an informed food choice. We also expect that these consumers may already check labels for potassium chloride since salt substitutes are permitted in non-standardized foods.

We agree that reducing sodium in the food supply may help reduce sodium intake, which in turn may help to reduce the risk of diet-related chronic disease, including hypertension, heart disease, and stroke. Reducing the risk of diet-related chronic disease may result in healthcare savings.

(Comment 6) A comment provided data on long-term modeling studies from various countries (e.g., China, India) to provide insight on effects of substitution of sodium chloride with potassium chloride. The comment suggests that there are limitations to the study including exclusion of patients with known kidney disease (those sensitive to increased potassium intake), ethnic variation, and other factors. The studies shared in the comment generally suggest that there are net benefits to policies that target substitution of sodium chloride with potassium chloride.

Some comments recommend that we conduct a modeling study to assess the impacts of “feasible” replacement of sodium with potassium on the diet and health of the U.S. population and specific at-risk populations, evaluating the effect of such intervention on recommended diets for at-risk populations and analyzing various costs of replacing sodium chloride with salt substitutes.

(Response 6) FDA acknowledges and appreciates the information provided by the comment in support of the final rule. The 2022 modeling study in India (Ref. 1) looked at replacing table and cooking salt with potassium chloride, and the 2020 study in China (Ref. 2) looked at replacing discretionary salt with potassium enriched salt substitutes. Both studies estimated a resulting increased risk of hyperkalemia in individuals with CKD. However, both studies also found that the public health benefits of salt substitution far outweigh public health risks. In addition, the final rule allows manufacturers to choose if and what salt substitutes to use for standardized foods (unlike the scenarios in the two studies that model replacing sodium chloride with potassium chloride, specifically, in all table salt). The final rule restricts the use of salt substitutes to levels no higher than necessary to achieve their intended purpose (and we expect that any use of potassium chloride to replace salt would be limited by impacts on taste). Furthermore, salt substitutes, including potassium chloride, are already permitted in non-standardized foods; product labeling, such as the Nutrition Facts label and ingredient list, informs consumers of the potassium content of the food. Given these differences, we do not believe that the studies are indicative of the effects of the final rule.

As noted in Response 1, FDA does not have access to the proprietary data, such as the number of products that may be reformulated, the level of salt replaced in the reformulations, or the demand for these newly reformulated products, necessary to assess the efficacy of the rule. We do, however, add a discussion of what public health outcomes could look like under certain assumptions about efficacy.

D. Summary of Changes

The public comments FDA received either provided support for the analysis, asked for clarification of content in the analysis, submitted studies addressing the potential public health outcomes of the rule, or recommended adding labeling requirements. In response to these comments, we have included more detailed discussions about the potential impacts of the rule to industry as well as to public health. We have also added a discussion of regulatory alternatives.

II. Final Economic Analysis of Impacts

A. Background

1. Deregulation Considerations

Executive Order 14192, Unleashing Prosperity Through Deregulation (90 FR 9065, February 6, 2025) directs agencies to eliminate unnecessary and burdensome regulations. Amending the SOI to allow salt substitutes is consistent with these directives as it eliminates the unnecessary restrictions on using salt substitutes. It is also consistent with section 6 of Executive Order 13563, “Improving Regulation and Regulatory Review” (76 FR 3821, January 21, 2011), which requires agencies to periodically conduct retrospective analyses of existing regulations to identify those “that might be outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them” accordingly.

2. Salt Substitutes

Salt substitutes are ingredients that can help reduce sodium in processed, packaged, and prepared foods. Manufacturers wishing to reduce salt in their products to accommodate consumer preferences or for other reasons sometimes use substitute ingredients that provide similar taste and other technical functions of salt in foods. Most of our SOI that include salt as a required or optional ingredient, however, do not permit the use of salt substitutes. Therefore, manufacturers are currently precluded from using salt substitutes in the production of these standardized foods.

The final rule amends the SOI to allow salt substitutes. Permitting the use of salt substitutes in standardized foods may contribute to our goal of reducing sodium across the food supply. It may facilitate voluntary industry efforts toward sodium reduction by providing flexibility and supporting innovation in the production of healthier standardized foods. This in turn may provide more choices to consumers and help some consumers to gradually reduce the sodium in their diet and contribute to better health outcomes. Reducing sodium may help reduce the risk of hypertension, a major risk factor for heart disease and stroke.

As more than 70% of Americans’ sodium intake comes from foods where sodium is added during food manufacturing and commercial food preparation, lowering population intake of sodium to more moderate levels involves lowering the amount of sodium added to commercially processed, packaged, and prepared foods (Ref. 3, 14). According to the Dietary Guidelines for Americans, the general population, ages 14 and above, should consume less than 2,300 milligrams/day (Ref. 4). For this reason, in addition to continued education initiatives, a multi-faceted approach is needed to help lower the burden of diet-related chronic disease, including providing consumers with information about sodium via nutrition labeling, encouraging sodium reduction in the food supply with our voluntary sodium reduction goals, and offering manufacturers the flexibility to use safe and suitable salt substitutes in standardized foods to allow for the development of lower-sodium foods. The final rule’s ingredient flexibility for the manufacturers of standardized foods

supports increased food choices for consumers seeking to lower sodium consumption that is consistent with recommendations of Dietary Guidelines for Americans.

B. Need for Federal Regulatory Action

Most SOI that specify salt (sodium chloride) as a required or optional ingredient do not permit the use of salt substitutes. Therefore, manufacturers are currently precluded from using salt substitutes in the production of these standardized foods and regulatory action is needed to mitigate associated market inefficiencies. For example, various parties have expressed concern that many SOI are out of date and may impede innovation, including the ability to produce healthier foods. Providing the option of using salt substitutes in standardized foods removes barriers to innovation and may also increase consumer surplus by providing healthier foods demanded by consumers and producer surplus by potentially leading to increased profits for manufacturers of standardized foods.

C. Purpose of the Rule

The purpose of the final rule is to amend FDA's definitions and SOI that specify salt (sodium chloride) as a required or optional ingredient. The amendments would permit the use of safe and suitable ingredients to replace some or all of the salt used in the manufacturing of standardized foods. Consequently, the final rule supports efforts to reduce sodium content in standardized foods and may help to improve consumer dietary patterns by reducing sodium consumption.

D. Baseline Conditions

The final rule amends 80 SOI that specify the use of salt. Because some of these 80 SOI are referenced by other SOI, there are a total of 139 SOI impacted by the final rule. The baseline of the final rule refers to the 139 SOI as currently written. The salt in the foods covered by these 139 SOI may serve a variety of functions such as taste, texture, moisture control, and microbial safety.

We use Circana data to capture the market size for product categories to which the 139 relevant SOIs belong. We rely on point-of-sale data from Circana to determine the count and sales of these products at multi-outlet and convenience retailers in 2024.¹ We do not perform manual UPC-level verification to determine whether each specific UPC within the relevant Circana product categories fall within the relevant SOIs. We therefore acknowledge that we likely overestimate the market size. We find that, in 2024, the sales of product categories to which the 139 relevant SOIs belong totaled \$78 billion, with about a quarter of a million UPCs sold. Because a single product formula may be sold under multiple UPCs — for example, the same formulation packaged in different sizes — we convert UPC counts to formula counts using a conversion rate of 0.8 formulas per UPC, consistent with the approach used in FDA's Front-of-Package Nutrition Labeling proposed

¹ Food and Drug Administration custom research definitions based on Circana, LLC (fka Information Resources Inc.) data 2024, dollar sales, unit sales, product name, and descriptive label variables, Total Multi Outlet with Convenience.

rule Preliminary Regulatory Impact Analysis.² We estimate roughly 200,000 unique product formulas fall within the product categories covered by the 139 relevant SOIs.

E. Benefits of the Rule

The benefits of the final rule come in the form of increased flexibility for manufacturers and potential public health benefits. Manufacturers would have additional flexibility in using salt substitutes when producing standardized foods covered by 139 SOI, which may lead to benefits in the form of increased consumer satisfaction (consumer surplus), increased profits (producer surplus), or both. Excess sodium intake increases the risk for hypertension, or high blood pressure, a leading cause of heart disease and stroke. If manufacturers of a standardized food deem reformulating their products using salt substitutes profitable, their reformulated products could lead to decreased consumption of sodium for consumers of those products, which could lead to public health benefits (Ref. 5, 6, 7, 8, 9).

To estimate the efficacy of this final rule, we would need to identify the costs and level of potential substitution, as well as the extent of consumer acceptance of salt substitutes at differing levels in different standardized foods. FDA does not have access to the proprietary data, such as the number of products that may be reformulated, the level of salt replaced in the reformulations, or the demand for these newly reformulated products, necessary to make these determinations. A study by Coxson et al. (2013) finds that a decrease in sodium consumption of 4 percent per year would lead to between 280,000 and 500,000 fewer deaths from stroke and cardiovascular and coronary heart disease over 10 years for U.S. adults ages 35 to 84 (Ref. 10). Because this final rule only affects the use of salt substitutes in a portion of total packaged food products, we do not expect this final rule will lead to similar levels of decreased sodium consumption. In Section II.L below, we describe the uncertainty surrounding the conditions that would allow meaningful health benefits to be realized.

F. Costs of the Rule

The final rule does not impose regulatory costs on manufacturers or consumers. There are no regulatory requirements or regulatory penalties relative to the baseline of taking no regulatory action. Manufacturers are required to use safe and suitable ingredients regardless of the amount or type of salt substitutes they choose to use (see 21 CFR 130.30(c)(1)). The flexibility provided by this rule creates parity for use of salt substitutes in standardized foods and such uses are required to be disclosed through existing labeling requirements.

The primary potential voluntary costs would arise from manufacturers choosing to use the flexibility afforded to them in the final rule to reformulate and re-label products (this includes

² Food Labeling: Front-of-Package Nutrition Information, Preliminary Regulatory Impact Analysis, available at <https://www.fda.gov/about-fda/economic-impact-analyses-fda-regulations/food-labeling-front-package-nutrition-information-proposed-rule>.

consumer testing and possibly marketing costs). Using FDA’s Labeling and Reformulation Cost Models (Ref. 11, 12), we estimate the per-UPC cost of a minor labeling change³ for an average food manufacturer to be between \$4,269 and \$14,679, and the per-formulation cost to be between \$3,000 and \$1.5 million. To the extent manufacturers choose to reformulate, any reformulations would be limited to the substitution of salt. This large cost range reflects the wide variation in food product complexity, company size, and the function of the salt being substituted. Because FDA does not have access to proprietary data on which manufacturers will reformulate, how many products they will reformulate, or the specific role salt plays in each affected formula, FDA cannot estimate aggregate industry reformulation costs.

Producers may choose to reformulate (and as a result, re-label) some standardized foods voluntarily in response to the rule’s added flexibility, and the magnitude of such costs would depend on the number of standardized foods reformulated. Regardless of the amount of reformulation manufacturers voluntarily choose to undertake, we expect they will only do so if their benefits in the form of increased revenue are at least as much as their costs.

The salt substitutes that manufacturers choose to use must not change the basic nature and essential characteristics of a standardized food (see 21 CFR 130.30(b)). This ensures that products manufactured with salt substitutes will retain their attributes. Thus, the extent to which salt can be replaced depends on the ability of the salt substitute to replicate the functions of salt in the food, including functions related to safety and quality. Food manufacturers are responsible for ensuring the safety of their food, regardless of whether they choose to use salt substitutes. A study by Hoppu et al. (2017) finds that salt substitutes may result in unfavorable changes to the flavor of a product, but also notes that formulation factors (e.g., the type and proportion of salt substitutes, the inclusion of flavoring extracts and compounds) can be altered to improve consumer acceptance (Ref. 13). We therefore expect that the final rule will not generate significant consumer dissatisfaction (in terms of product attributes, quality, and safety) relating to the standardized food.

G. Transfers Caused by the Rule

We do not expect the final rule to cause any form of transfers.

H. Summary of Benefits, Costs, and Transfers

The final rule permits manufacturers of standardized foods that use salt as an ingredient in their food products to use salt substitutes. Considering the voluntary nature of the final rule, there are no regulatory costs associated with the final rule. Other costs considered include voluntary reformulation and re-labeling costs, as well as consumer dissatisfaction with altered product properties. The benefits of the final rule include producer surplus (increased profits for the manufacturer) and increased consumer surplus (healthier food choice that satisfies consumer

³ Updating the ingredients list, Nutrition Facts.

demand). In addition, there may be public health benefits that come from reduced sodium consumption in the form of reduced incidences and deaths from cardiovascular disease.

I. Analysis of Regulatory Alternatives to the Rule

3. Allow salt substitutes only for standardized foods with salt as an optional ingredient, but not for standardized foods with salt as a mandatory ingredient, or only for certain product classes of standardized foods.

This regulatory alternative would restrict the flexibility of the rule and lessen the potential for reduced sodium consumption by the public. For example, only allowing salt substitutes for standardized foods with salt as an optional ingredient would not allow salt substitutes to be used in cheeses, which would significantly reduce the scope of the rule. As shown in the costs and benefits analyses, reduced sodium consumption by the public is expected to yield public health benefits. This regulatory alternative would reduce flexibility for industry and likely lead to lower public health benefits.

4. Allow only specific salt substitutes (e.g., potassium chloride) in standardized foods.

As with the above alternative, this would restrict the flexibility of the rule and lessen the potential for reduced sodium consumption by the public. Manufacturers who would prefer using a salt substitute that is not permitted by this regulatory alternative may decide to forgo sodium reduction altogether. This regulatory alternative would reduce flexibility for industry and likely lead to lower net public health benefits.

J. Distributional Effects

Given the voluntary nature of the final rule, we do not have sufficient information to estimate the benefits, costs, and transfers to any particular segment of the public or entities.

K. International Effects

We do not expect that the final rule will have any effects on foreign entities. As with domestic manufacturers, foreign manufacturers of standardized foods have the option to use salt substitutes to reduce the sodium content of their standardized foods. There would be no regulatory requirements or regulatory penalties relative to the baseline of taking no regulatory action for international manufacturers.

L. Uncertainty and Sensitivity Analysis

In this section, we discuss the sources of uncertainty in the analysis. Due to the voluntary nature of the rule and the lack of pertinent data, we are unable to estimate, or evaluate the magnitude of, any potential voluntary industry costs and public health impacts of the rule. For purposes of this

analysis, we identify how many product formulas would need to be reformulated to reach the \$100 million threshold for economic significance.

The primary source of uncertainty in this analysis is the unknown behavioral response of both manufacturers and consumers to the final rule. Because the rule is entirely voluntary, FDA cannot predict whether, or to what extent, manufacturers will choose to reformulate standardized foods using salt substitutes. Manufacturers will only undertake reformulation if they expect the resulting benefits, in the form of increased revenue or market share, to at least offset their costs.

As discussed in Section II.F above, FDA's Reformulation Cost Model produces per-formulation estimates that range from approximately \$3,000 to approximately \$1.5 million, reflecting the wide variation in food product complexity, company size, and the function of the salt being substituted. Thus, between 67 and 33,333 reformulations would be needed to reach the \$100 million threshold for economic significance. This represents between less than a tenth of a percent (0.03 percent) to 17 percent of the roughly 200,000 formulas potentially affected by the rule, as described in Section II.D.

Allowing manufacturers of certain standardized foods to voluntarily replace some or all of the salt with salt substitutes carries significant uncertainty regarding the extent of the health benefits. Although reducing dietary sodium to lower cardiovascular disease risk is a well-supported public health goal, realizing measurable population-level benefits through this voluntary mechanism depends on several conditions including whether (1) manufacturers choose to reformulate their products, (2) consumers are willing to consume those reformulated products and decrease their total sodium intake, and (3) the degree of sodium reduction in the affected consumers' diet based on the type and proportion of salt substitutes used, and the function of salt in each food. The limitations of available data introduce meaningful uncertainty into both the magnitude and distribution of potential public health benefits.

III. Final 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 the rule would not impose regulatory costs on small entities, we certify that the final rule will not 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 Final Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

IV. References

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