DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Docket No. FDA-2022-N-2226

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

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Preliminary Economic Analysis of Impacts

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (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 (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Office of Information and Regulatory Affairs has determined that this proposed rule is a significant regulatory action as defined by Executive Order 12866 Section 3(f)(1).[1]

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. We do not anticipate the proposed rule would generate regulatory impacts on small entities. As with any voluntary market behavior, larger firms may have certain advantages over small firms in some areas, while smaller firms may have advantages in other areas. As a result, we propose to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by

[1] We note that this Executive Order 12866 applies only to the non-dairy SOI portions of this rulemaking; the dairy SOI covered by this rulemaking are "regulations or rules issued in accordance with the formal rulemaking provisions of 5 U.S.C. 556, 557" (see 21 USC 701(e)(1)) and therefore excluded by section (d)(1) of Executive Order (EO) 12866.

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 million, using the most current (2021) Implicit Price Deflator for the Gross Domestic Product. The proposed rule would not result in a mandated expenditure in any year that meets or exceeds this amount.

The proposed rule would permit, but not require, manufacturers to use salt substitutes to replace salt where salt is a required or optional ingredient in standardized foods. If finalized, the benefits of this rule would be additional flexibility in the manufacture of standardized foods and the potential for reduced salt consumption by consumers which may contribute to better health outcomes. We have no information to suggest the use of currently available salt substitutes would lead to improved product characteristics (e.g., shelf life) or would lead to reduced production costs and potentially lower prices. We request comment on such potential benefits of reformulation for manufacturers and on how many standardized foods manufacturers might choose to reformulate, either in the relatively near or longer-run future.

The proposed rule, if finalized, would not impose requirements resulting in regulatory costs on firms or consumers. Manufacturers would have the *option* of using salt substitutes. There are no regulatory implications for not reading the rule or deciding not to use salt substitutes. Should manufacturers choose to use this flexibility to reformulate some products by substituting some salt with salt substitutes, the primary benefits realized would result from lower sodium consumption on average by U.S. consumers, assuming they choose to purchase and consume the reformulated versions of such products, and increased profit (producer surplus) for manufacturers, assuming they find offering reformulated versions of such products consistent with maximizing firm profits. The primary costs of such voluntary market behavior would be

reformulation and relabeling costs for manufacturers. We currently lack data to estimate any net social benefits from voluntary market behavior relating to future use of salt substitutes made possible by this rule, but cite some published analyses below related to meeting voluntary sodium reduction targets that could partially be addressed via the flexibility provided by this rule. We request public comment on possible producer response (e.g., how many manufacturers may choose to take voluntary action in response to this rule, what share of standardized food products may get reformulated) and on possible consumer willingness to purchase and consume such products with various types of salt substitutes at various levels, which would allow us to provide a range of net social benefit estimates when this rule is finalized.

A. Economic Analysis of Impacts

1. Background

There are 80 SOI that specify salt as a mandatory or optional ingredient. Some of these standards are referenced by other SOI, resulting in salt as an ingredient in 140 SOI. The salt in the foods covered by these 140 SOI may serve a variety of functions such as taste, texture, moisture control, and microbial safety. FDA has a public health interest in reducing sodium across the food supply. Therefore, we propose to give manufacturers the flexibility to use salt substitutes in standardized foods where salt is a required or optional ingredient, to reduce the sodium content. While there may be potential data sources (e.g., IRI, Label Insight, Mintel, NHANES, Syndigo) that could provide market or consumption share (e.g., contribution of sodium and/or caloric intake) for foods covered by these 140 SOI, FDA does not currently have sufficient estimates to further extrapolate impacts at this time. We request public comment on additional potential data sources for estimates of market share and/or caloric and/or sodium consumption share of the products included in these SOI.

We request comment on potential regulatory alternatives including 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. More generally, we request comments on potential regulatory approaches to reducing salt in food or the dietary intake of salt that do not involve allowing the use of salt substitutes in standardized foods.

2. Benefits of the Proposed Rule

The benefit of this proposed rule is that manufacturers would have additional flexibility in producing standardized foods covered by 140 SOI, which may lead to social benefits in the form of increased consumer satisfaction (consumer surplus), increased profits (producer surplus), or both. In addition, a change in voluntary market behavior relating to patterns of food consumption, or to use a potassium-based salt as a salt substitute and consumers who would benefit from increasing their potassium intake choose to consume those products, those consumers may experience positive health effects.

Salt is a relatively inexpensive ingredient, and we would not expect manufacturers to begin using salt substitutes based on cost cutting considerations alone at this time. To explore the possibility of manufacturers voluntarily replacing salt with salt substitutes to improve the healthfulness of their standardized foods, one would need to identify the costs and level of potential substitution, and extent of consumer acceptance of salt substitutes at differing levels in different standardized foods in order to estimate the number of manufacturers who would decide to use salt substitutes. We currently lack data on these potential industry responses and request public comment from manufactures, suppliers, and consumers on the extent to which the

additional flexibility provided by this rule would be used by manufacturers, hence also desired or tolerated by consumers, and viable in the supply chain.

As discussed in the preamble of this rule, on average, Americans consume approximately 3,400 milligrams of sodium per day (mg/day), which is nearly 50 percent more than the recommended daily limit on sodium intake for individuals 14 years and older (Refs. 1 and 2). Excess sodium intake increases the risk for hypertension, or high blood pressure, a leading cause of heart disease and stroke (Refs. 2-6). Decreasing sodium consumption is expected to reduce hypertension and potentially result in fewer cases of heart disease and stroke (Refs. 7-9[2]). More than 70 percent of sodium consumed in the U.S. comes from sodium added during manufacturing and commercial food preparation (Ref. 14). The health benefits from reducing sodium consumption are expected to be higher for populations that currently have higher sodium consumption or that are more sensitive to any given level of sodium consumption than other populations. Hence, there may be potential health equity effects to any regulation that generates or facilitates reduced intake of sodium. In order to estimate such health benefits, we would need data and information on the complex pathway between allowing manufactures to use salt substitutes, the extent to which manufactures will develop products of interest to those at highest risk of hypertension, the likely demographic patterns of consumers purchasing those new products, and eventually, the extent of the reduction in sodium uptake among those at most risk of hypertension.

In the absence of necessary data to fully estimate the impacts of this rule, we refer to published literature on the health benefits of sodium reduction targets to provide broader context

[2] These studies may be sensitive to assumptions regarding consumer response. If some consumers experience disutility associated with the reformulated product and adjust their consumption pattern accordingly, this could partially offset some of the estimated health benefits.

of potential impacts of this rule. A 2018 study by Pearson-Stuttard, et al. looked at the health and economic effects of FDA's 2016 draft voluntary sodium reduction guidance (Refs. 8 and 22) and estimated benefits of meeting sodium reduction targets in the form of medical cost savings and consumer health improvements, net of producer reformulation costs and some government administrative and monitoring costs. Over a 20-year period, the authors of the study find net social benefits from only consumer health effects to be roughly $12 billion (uncertainty range of $0 billion to $28 billion) under what it described as the most pessimistic scenario relating to potential sodium reduction among the three presented (Ref. 8). This roughly $12 billion *net* benefit arises from roughly $19 billion in estimated health cost savings (benefits) and just over $7 billion of estimated reformulation, administrative and monitoring costs[3].

Since these benefit estimates are not comprehensive, we would need additional data on possible producer and consumer response to fully assess health benefits. Moreover, benefits might be higher or lower than what would be indicated by estimates that focus on the subset of effects tracked by Pearson-Stuttard et al. Benefits might be higher if firms were to realize additional profits or producer surplus from any product reformulation (since we assume firms would use salt substitutes only if profits would remain the same or increase). Benefits might also be higher due to possible changes in consumer surplus from consumers willing to buy reformulated products whose valuation includes factors beyond medical cost savings or health state utility. Benefits might be lower if some consumers experience disutility associated with the reformulated product and adjust their consumption pattern accordingly, which could partially offset the estimated health benefits presented above.

[3] These results may be sensitive to assumptions regarding consumer response to product reformulation. For example, benefits might be lower if some consumers experience disutility associated with the reformulated product and adjust their consumption pattern accordingly, which could partially offset the estimated health benefits presented above. Ref. 9, for instance, indicates that its cost-effectiveness results are highly sensitive to such issues.

In addition, as mentioned above, we currently lack data to determine how much, if any, of the aggregate effects that Pearson-Stuttard et al. attribute to broader voluntary sodium reduction efforts could be directly connected to the flexibility provided by this rule. The rule does not cover all foods analyzed in the Pearson-Stuttard, et al. scenarios, which included many non-standardized foods. With comprehensive data on the share of foods affected by this rule, we could estimate health benefits across only such products as a subset of the Pearson-Stuttard, et al. estimate. We request such data and also data on possible consumer and producer response to the flexibility provided by this rule.

3. Costs of the Proposed Rule

The proposed rule, if finalized would not impose *regulatory* costs on manufacturers or consumers. There would be no regulatory requirements or regulatory penalties relative to the baseline of taking no regulatory action. Manufacturers would be required to use safe and suitable ingredients regardless of the amount or type of salt substitutes they choose to use. The flexibility provided by this rule creates parity for use of existing salt substitutes in both standardized and non-standardized foods (see section V.C. for discussion of examples of current salt substitutes in use) and such uses are already required to be disclosed and labeled. It is possible that a change in voluntary market behavior relating to food consumption may generate health costs. For example, to the extent manufacturers choose to use potassium chloride as a salt substitute and consumers choose to consume those products, consumers who may need to limit their potassium intake may see negative health effects that should be accounted for in cost estimates. We request comments on evidence that could contribute to a more thorough

assessment (including possible quantification) of such costs. The agency will continue to monitor the use of salt substitutes in the U.S. food supply.

The economic rationale for food standards involves reducing consumers' search costs; in particular, their ability to infer certain product characteristics from representation as certain standardized foods. The proposed rule may affect product characteristics by allowing manufacturers to use salt substitutes that replace any one or any combination of the functions of added salt. However, the proposed rule would preclude ingredient substitutions that change the basic nature and essential characteristics of a standardized food. The basic nature of a food concerns the general attributes of the product that is offered for sale to consumers. The essential characteristics of a food may contribute to achieving the basic nature of the food, but consumers may not be aware of the essential characteristics. Use of safe and suitable salt substitutes that do not change the basic nature and essential characteristics of the standardized food ensures that products on the market retain their general attributes. For purposes of this analysis, we assume products that retain their general attributes will also retain consistency with consumer beliefs and expectations relating to those products and that the use of salt substitutes will therefore not generate consumer dissatisfaction relating to the identity of the standardized food. To the extent that this assumption may not be accurate, we request comment on the degree to which consumers may be willing to purchase and consume such products after salt substitutes are used.

If finalized, manufacturers may choose to take advantage of the flexibility provided in this proposed rule. As discussed above, the primary potential costs of that voluntary market behavior would arise from producers choosing to use the flexibility afforded to them to reformulate some products such as reformulation, consumer testing, labeling, and possibly marketing costs. Pearson-Stuttard, et al., estimate that reformulation costs (using the FDA

model, Ref. 23) corresponding to the draft voluntary short term sodium reduction targets could range from $2.7 to $15 billion over a 20-year time period and that these costs would comprise roughly 95 percent of the costs related to reaching short term sodium reduction targets (Ref. 8). Producers may voluntarily choose to reformulate some products in response to this rule's added flexibility and the magnitude of such costs would depend on the number of products reformulated. The more firms choose to reformulate using salt substitutes given the flexibility provided by this rule, the greater the share of sodium reduction efforts (and associated reformulation costs) that could be attributed to this rule. Regardless of what amount of reformulation producers voluntarily choose to undertake, they will only do so if their private benefits in the form of increased revenue are at least as much as their private costs. We request comment on the number of manufacturers who may choose to reformulate standardized food products and the extent to which manufacturers may choose to reformulate those products given this new flexibility. We also request comment on all other considerations relating to manufacturers' voluntary market decision to use salt substitutes including cost of reformulation, ability to source substitute ingredients, expected impact on sales, profits, and consumer acceptance or lack of acceptance.

B. 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. If finalized, we do not expect the proposed rule would generate impacts on small entities. The rule would not impose regulatory costs on small entities. There would be no regulatory requirements or regulatory penalties relative to the baseline of taking no regulatory action. We have no basis to suppose or estimate any other impacts on small entities. As a result, we propose to certify that the proposed

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 Initial Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

This analysis is also available in the docket for this proposed rule (Ref. 24) and at https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations.

References

The following references marked with an asterisk (*) are on display with the Dockets Management Staff (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at http://www.regulations.gov. References without asterisks are not on public display at http://www.regulations.gov because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

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