



# Will Food and Drug Administration Guidance to Reduce the Salt Content of Processed Foods Reduce Salt Intake and Save Lives?

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In this issue of *Hypertension*, Song et al<sup>1</sup> report results from modeling studies showing that thousands of premature deaths might have been averted if the Food and Drug Administration (FDA) had acted sooner in finalizing guidance on reducing the amount of salt added to processed, packaged, and prepared foods. In October 2021, FDA officially issued guidance on food salt reduction targets for industry.<sup>2</sup> According to the modeling studies of Song et al, as many as 265 000 lives might have been saved if the FDA had finalized their guidance for industry in 2016 when the salt reduction targets were originally drafted.<sup>1</sup> A major strength of this important article is the inclusion of modeling studies predicting that thousands of deaths might have been averted by earlier FDA guidance even if industry only partially complied with the salt reduction targets. As in the United States, many countries worldwide are interested in the use of food salt reduction programs to stem the pandemic of hypertension and cardiovascular disease. Thus, the profound prediction of the modeling work of Song and colleagues has global health implications and merits careful consideration. Consequently, when evaluating this prediction, it is important for readers to keep in mind that these modeling studies, like other modeling studies of complex phenomena related to changes in salt intake,<sup>3</sup> depend on some critical assumptions.

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The modeling studies of Song et al specifically depend on at least 2 major assumptions. First, it is assumed that

reducing the concentration of salt in various foods will substantially reduce mean salt intakes of men and women in the general population. Second, it is assumed that a reduction in mean population salt intake in countries like the United States will reduce risk for premature death and disability from cardiovascular disease. The second assumption is intensely debated by respected scientists on both sides of the issue and remains highly controversial.<sup>4</sup> In contrast, the first assumption has received far less scrutiny. What is the evidence that reducing food salt concentration will cause a substantial decrease in mean salt intake in the general population? This question pertains directly to modeling studies which estimate the number of lives saved contingent on the extent to which population salt intake is reduced after issuance of salt reduction targets for industry.

The United Kingdom is the only region in which population salt intake has been serially monitored with rigorous 24-hour urine sodium measurements before and repeatedly after introduction of a food salt reformulation program. The UK Food Standards Agency first issued salt reduction targets for the food industry in March 2006. Within 3 years of publication of the targets, the salt content of most processed foods in UK supermarkets was reduced by 20% to 30%.<sup>5</sup> Between 2009 and 2017, the sodium density of all foods consumed in the United Kingdom (excluding beverages, fruit juices, and added table salt) was reported to have decreased by 21%.<sup>6</sup> How much impact did this substantial reduction in food salt content have on mean salt intake in the population? The answer to this question may come as a surprise.

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Contrary to expectations, reports by Public Health England (PHE) show that in women in England, mean salt intake did not significantly decrease at any time after publication of the food salt reduction targets in March 2006 (Figure).<sup>7</sup> In men, there was a statistically significant reduction in salt intake of 0.8 g/d in 2008 with no significant changes in salt intake after 2008 (Figure).<sup>7</sup> Moreover, according to the trend analysis by PHE, there has been no statistically significant linear change in general population salt intake over time since publication of the salt reduction targets (Figure).<sup>7</sup> The failure of salt intake to show a significant decline in women at any time is particularly noteworthy because (1) the surveys on salt intake involved more women than men and (2) the public health awareness campaign that was conducted before, during, and after launch of the food reformulation program mainly targeted women.

Proponents of the population food salt reduction program recently claimed that salt intake in the general population declined by 15% after publication of the UK food salt reduction targets.<sup>8</sup> However, according to PHE, the estimate of 15% is open to question because it (1) is based on sodium results that were not corrected for method specific analytical bias and (2) involved data on baseline salt consumption (before food reformulation) that PHE deemed inappropriate for use in the trend analysis of salt intake.<sup>7</sup> In this issue of *Hypertension*, Song et al state that the food salt reduction program caused salt intake to decline by 10% (men and women combined). However, this statement seems to contradict the trend analysis by PHE showing little or no impact of the food salt reduction program on salt intake in the general population of England (Figure).<sup>7</sup> Given the findings of PHE, it is helpful to understand how Song et al calculated the decline in salt intake that occurred after introduction of the salt reduction targets.

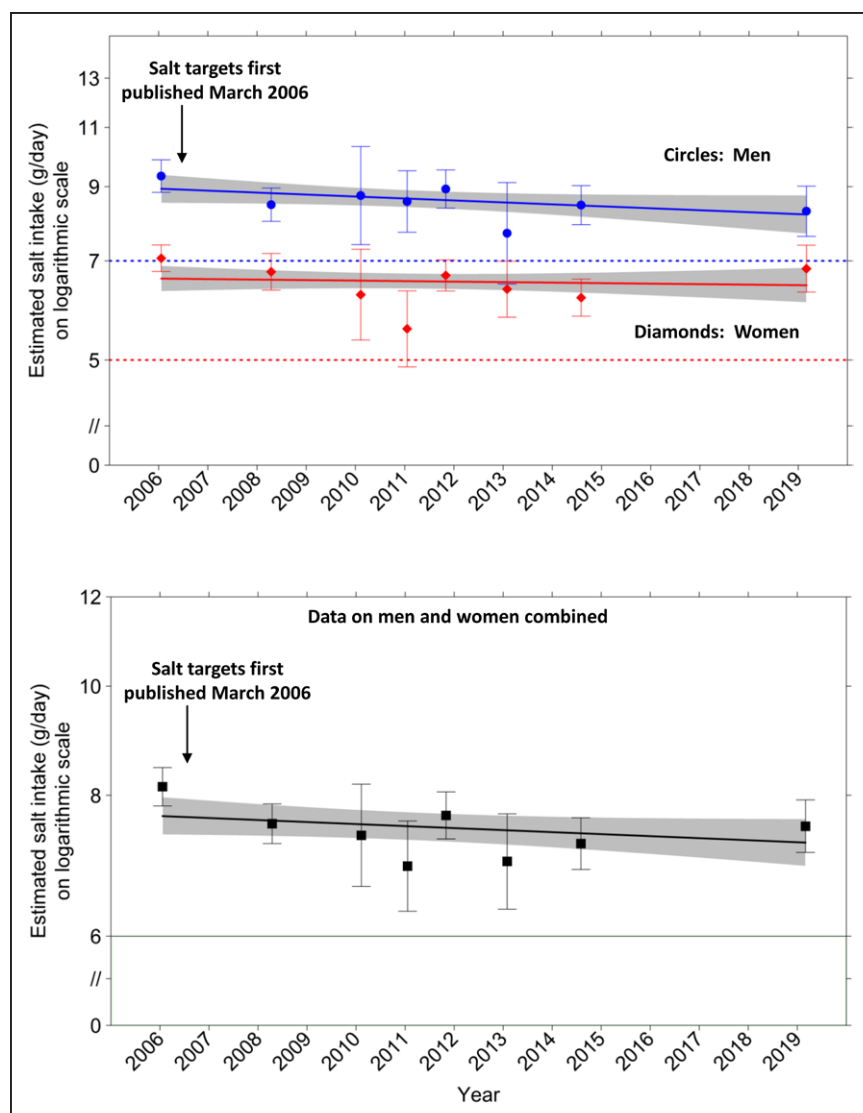
In calculating the change in salt intake associated with food salt reduction, Song et al compare intake data from 2006 (just before publication of the salt targets) to data from 2011, that is, to data obtained 5 years after release of the targets. Thus, the authors selected and analyzed a specific year (2011) that supported their contention out of the entire 13-year period that followed publication of the salt targets. It is important for readers to recognize that if one selects and analyzes salt intake results for the year 2010 or 2012 as reported in data tables released by PHE,<sup>7</sup> the change in salt intake in England after introduction of the food salt targets in 2006 is not statistically significant. When visualizing the data from all the years (Figure), it appears that the lower level of salt intake in 2011 may have been due to random variation in estimates of population salt intake over time and not due to removal of salt from the food supply. PHE's comprehensive analysis showed that mean salt intake decreased between 2006 and 2008 without any significant decrease thereafter.<sup>7</sup> Furthermore, the decrease

was statistically significant only in men. Inexplicably, the disparity in results between men and women has received little or no attention and merits future investigation.

Why would food salt reduction have little or no impact on population salt intake as shown by the reports from PHE?<sup>7</sup> One of the factors emphasized by Song et al is a lack of compliance by the food industry in meeting the food salt reduction targets. Thus, it is important to understand the extent to which industry reduced the amount of salt added to processed foods in England after publication of the salt reduction targets. Recently, senior coauthors of the current article by Song et al noted that "By getting all companies to work toward the same targets, the United Kingdom has achieved a 20% to 50% reduction in the salt content of many food products over a decade."<sup>9</sup> Consistent with this view, Gressier et al<sup>6</sup> reported that between 2009 and 2017, there was a significant 21% reduction in the sodium density of all foods consumed in the United Kingdom (excluding beverages, fruit drinks, and added table salt).<sup>6</sup> Thus, lack of compliance by the food industry would not seem to explain the failure of population salt intake to decrease as many expected. Furthermore, lack of compliance by the food industry cannot explain the failure of salt intake to decrease in women at any time after publication of the salt targets.

When considering whether food salt reduction programs will reduce salt consumption, it is useful for the reader to keep in mind that salt intake is determined by several factors beyond simply the concentration of salt in food products. In addition to food salt concentration, salt intake is determined by the amount of food ingested, the proportions of the various salty food products ingested, and the amount of salt added to food by the consumer. In response to progressive reductions in salt concentration across multiple foods, it has been proposed that individuals may begin to add more salt to their food, consume more food, or consume greater quantities of the saltier foods to maintain their physiologically desired levels of salt intake.<sup>10,11</sup> Studies of salt intake in response to reducing salt concentration in only a single type of food<sup>12</sup> do not address the effects of reducing salt concentration in most of the food supply.

According to the work of McCarron et al,<sup>11</sup> the lower normal physiological limit for mean salt intake in populations of healthy, free-living individuals is  $\approx 6$  to 7 g/d for women and 8 to 9 g/d for men. Less than 2.5% percent of populations worldwide have mean salt intakes below these ranges including in regions where consumption of processed foods is low.<sup>11</sup> McCarron et al<sup>11</sup> have noted that these findings are consistent with physiological control of salt intake. In parts of China in which consumption of manufactured foods is negligible, mean salt intake is higher than recommended because people choose to add large amounts of salt to their food at home.<sup>13</sup> These observations indicate that humans consume considerable



**Figure. Analysis by Public Health England of salt intake of adults in England before and after the UK Food Standards Agency publication of salt reduction targets for the food industry in March 2006.<sup>7</sup>**

The salt intake results are geometric means and 95% CIs for the geometric means. The gray shaded regions indicate the 95% CIs for the regression lines.

**Upper** shows the separate results for men and women. The dashed lines indicate the UK population target for maximum salt intake in men of 7 g/d and in women of 5 g/d. The slope of the line for salt intake per year is not significantly different from zero for men ( $P=0.07$  [95% CI,  $-1.4\%$  to  $0.1\%$ ]) or for women ( $P=0.61$  [95% CI,  $-0.8\%$  to  $0.5\%$ ]).<sup>7</sup> The change in salt intake for men between 2006 (just before publication of the food salt targets) to 2009 was statistically significant with no significant step change thereafter.<sup>7</sup> In women, there was no significant change in salt intake at any time after publication of the salt reduction targets.<sup>7</sup> **Lower** shows the results for men and women combined. The slope of the line for salt intake over time is not significantly different from zero ( $P=0.09$  [95% CI,  $-0.9\%$  to  $0.1\%$ ]).<sup>7</sup> The horizontal line is the UK target maximum for salt intake in the general population of 6 g/d. Note that the target for maximum salt intake recommended by the World Health Organization is 5 g/d. Details on the graphs and the analysis by Public Health England are available at [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/876252/Report\\_England\\_Sodium\\_Survey\\_2018-to-2019\\_3\\_.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/876252/Report_England_Sodium_Survey_2018-to-2019_3_.pdf).

amounts of salt regardless of whether industry is producing foods with high salt content. It has been contended that attempts to lower mean population salt intake below these levels by reducing salt concentration in most foods might prove futile (because individuals may modify their eating habits to maintain salt intake at their physiologically desired limits).<sup>11</sup> In the US and UK populations, mean salt intakes are already close to the lower normal physiological limits for mean salt intake suggested by the analysis of McCarron et al.<sup>11</sup> This raises the possibility that in England, the failure of food salt reduction to affect mean salt intake in women may be due to the fact that mean salt intake in women was closer to the lower normal physiological limit than mean salt intake in men when the salt reduction targets were introduced.

South Africa is one of the only other countries in which salt intake has been assessed by measurements of 24-hour urine sodium excretion before and after introducing a food salt reduction program.<sup>14</sup> A statistically significant reduction in salt intake could be shown only

after adjusting the salt intake data for nearly a dozen other variables.<sup>14</sup> Alarming, the introduction of mandatory food salt targets in South Africa was also associated with a significant increase in diastolic blood pressure, a significant decrease in potassium intake (as judged by urinary potassium measurements), and no change in systolic blood pressure.<sup>14</sup>

In summary, when evaluating the predictions of the interesting modeling studies by Song et al, it is important to understand the impact of food salt reduction on salt consumption in high income countries like England and the United States. Based on the findings of PHE, it is questionable whether substantial reductions in food salt concentration can substantially reduce mean salt intake in the general population. Thus, even if industry complies with FDA guidance on food salt targets and meets the goal of reducing food sodium concentration by  $\approx 15\%$ , it is uncertain whether this will cause a significant reduction in salt intake in the United States. Given this uncertainty, it should be noted that investigators are

developing methods for protecting against the adverse effects of salt on blood pressure and cardiovascular risk that require little or no reduction in salt intake.<sup>10,15–17</sup>

## ARTICLE INFORMATION

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