

The Sodium Conundrum

Evolving Recommendations and Implications

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The potential contribution of sodium to chronic disease risk has been an area of exploration for many years. Currently, a National Academies of Sciences, Engineering, and Medicine committee is working to update the 2005 Dietary Reference Intakes for sodium and potassium, evaluating the latest evidence with a look to excesses, inadequacies, and chronic disease risk reduction. Two recent reports will support the National Academies of Sciences, Engineering, and Medicine review: a systematic review of the science related to sodium, potassium, and chronic disease and guidelines for considering chronic disease in setting dietary reference intakes. While sodium intake reduction initiatives have been underway for years, current intake estimates significantly exceed recommendations. Recently, the US Food and Drug Administration issued draft guidance on voluntary sodium reduction targets for 150 food categories. This review is based on a session at the American Society for Nutrition 2018 Annual Meeting, which brought together stakeholders to discuss these developments, progress, conundrums, and opportunities toward reducing sodium intakes. *Nutr Today*. 2019;54(1):31–41

US policy makers have recommended that sodium be reduced in the American diet for almost 50 years. The current average intake for the US population is 3409 mg/d,¹ well above the 2005 Dietary Reference Intake

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ML received travel support and funding from ILSI North America to prepare this summary.

This article is based on the session “The Sodium Conundrum—Evolving Recommendations and Implications” held at the American Society for Nutrition 2018 Annual Meeting in Boston, Massachusetts. The symposium was sponsored by the North American Branch of the International Life Sciences Institute (ILSI North America) Sodium Committee. ILSI North America is a public, nonprofit scientific foundation that provides a forum to advance understanding of scientific issues related to the nutritional quality and safety of the food supply by sponsoring research programs, educational seminars and workshops, and publications. ILSI North America receives support primarily from its industry membership. The opinions expressed herein do not necessarily represent the views of the funding organization.

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DOI: 10.1097/NT.0000000000000321

(DRI) values for sodium. The DRIs are 1500 mg/d for an Adequate Intake (AI), and a Tolerable Upper Intake Level (UL) of 2300 mg/d.² The 2015–2020 Dietary Guidelines for Americans recommend that Americans consume less than 2300 mg of sodium each day as part of a healthy-eating pattern.³ Achieving these recommendations has proven difficult, and sodium intakes have remained relatively constant over time.⁴ Consuming too much sodium remains a valid concern. Various expert panels have assessed the science with differing conclusions, yet there is general agreement that lowering sodium intake reduces high blood pressure, that is, hypertension risk. Hypertension is a validated surrogate end point reflective of risk of stroke, myocardial infarction, and mortality.⁵ There is also emerging evidence of the protective role of potassium on hypertension, independently or through its influence on the body’s management of sodium. A session at the American Society for Nutrition 2018 Annual Meeting organized by the North American branch of the International Life Sciences Institute brought together stakeholders to review recent developments to better understand the relationships between sodium intakes and chronic disease, and progress and challenges related to sodium reduction in the food supply. This article reviews these presentations and discussions.

Various expert panels have assessed the science with varying results, yet there is general agreement that lowering sodium intake reduces hypertension. Hypertension is a validated surrogate end point reflective of risk of stroke, myocardial infarction, and mortality. There is also emerging evidence of the protective role of potassium on hypertension, independently or through its influence on the body’s management of sodium.

Policy initiatives aimed at reducing sodium intake have been ongoing. In 2010, an Institute of Medicine (IOM) report provided recommended strategies for lowering sodium in the food supply.⁶ Key points included a need to involve the entire food supply as well as to facilitate a response by manufacturers in companies of trying sizes. There have been multifaceted efforts to reduce sodium intakes, including consumer education, but given that more than 70% of dietary sodium comes from commercially processed and prepared foods, it is difficult for individuals to control sodium intake. Despite industry successes in reducing the sodium content of certain foods, many foods continue to contribute substantial amounts of sodium to the diet. Sodium reduction poses technical challenges to food manufacturers, given its role in taste, safety (controlling bacterial growth and spoilage), maintenance of texture and color, extending shelf life, and reducing cost.

Sources of sodium in the diet of the US population are widespread throughout the food supply. Analysis of the most recent US intake data, from 2013 to 2014 What We Eat in America, the dietary intake data portion of the National Health and Nutrition Examination Survey (NHANES), reveals that on average the US population 2 years or older consumed 3409 mg of sodium daily.¹ This value does not include salt added at the table. Table 1 provides information on sources of sodium in the American diet.

There have been considerable efforts in sodium reduction by the food industry over the past 10 years. Challenges remain in assessing the body of science related to sodium and health outcomes, monitoring and evaluating sodium intake, and in reducing sodium in the food supply. Many efforts are underway to improve the understanding of sodium and health relationships and the role of sodium in foods to better enable science-based policies.

THE PROCESS FOR UPDATING THE DRIs, WITH FOCUS ON SODIUM

The DRIs are a set of reference values used to plan and assess nutrient intakes of healthy people. These are developed for use by the US and Canadian governments for several purposes, including dietary guidelines, nutrition policies, nutrition monitoring, and in nutrition labeling and research, for use by the military and food and supplement industries, to name a few. The 2005 IOM report established the AI for sodium at 1500 mg/d and the UL at 2300 mg daily for adults.² The AI for potassium for adults was set at 4700 mg/d, with no UL set, given no evidence of adverse effects from potassium consumed from foods. Data were inadequate to set an Estimated Average Requirement (EAR) for both nutrients. Table 2 provides the basis for the AI and ULs set for sodium and potassium.

The US and Canadian governments have partnered to develop the DRIs since the mid-1990s. A joint Canadian

TABLE 1 Facts on Sodium Sources in the Diet¹

- On average, the US population 2 y or older consumed 3409 mg of sodium daily.
- Sodium is dispersed throughout the food supply, with 70% of dietary sodium coming from 25 food categories. No single category comprises more than 7% of intakes overall. Breads were the top contributor, accounting for 6% of sodium consumed.
- Most of the sodium consumed came from foods purchased at stores (61%); however, sodium density (mg per 1000 kcal) was highest in foods obtained at restaurants.
- Foods obtained from restaurants with wait staff were the most sodium-dense.

Values cited do not include salt added at the table.

and US working group has the goal to develop an efficient process that ensures DRI values continue to be accurate and founded on current evidence. The collaboration's aim is to identify DRI needs, prioritize nutrient reviews, and advance work to resolve methodological issues that could impact future reviews. In 2013, the working group conducted a DRI nomination process to help plan for new DRI reviews of nutrients and related substances reviewed in previous DRI reports. A key requirement was that new science be available for consideration.⁷ Sodium was 1 of 4 nutrients prioritized for further consideration. Also, Congress recently directed that an update of the 2005 sodium DRIs be conducted. Given the physiologic and health interrelationships of sodium and potassium, potassium is included in the review. The Health and Medicine Division (HMD, formerly the IOM) of the National Academies of Sciences, Engineering, and Medicine is responsible for this work; an expert committee has been convened, and its work is underway,⁸ with the final report anticipated in early 2019. The review will include consideration of 2 new reports. The first, the 2017 National Academies of Sciences, Engineering, and Medicine report on Guiding Principles for the Inclusion of Chronic Disease Endpoints in Future Dietary Reference Intakes,⁹ provides guidelines and a more specific framework for considering chronic disease end points. The second, a systematic evidence review conducted by the Agency for Healthcare Research and Quality (AHRQ), was commissioned to address questions on the evidence linking sodium and potassium to cardiovascular and renal outcomes.¹⁰

The new DRI review will consider indicators of deficiency, inadequacy, and toxicities, as well as relevant chronic disease end points. Sponsors include Health Canada, National Institutes of Health, US Centers for Disease Control and Prevention, US Food and Drug Administration (FDA), US Department of Agriculture, and Public Health Agency of Canada. While the DRI review panel will consider the

TABLE 2 2005 Adequate Intakes and Tolerable Upper Intake Levels for Sodium and Potassium²

	Sodium	Potassium
Adequate Intake (AI)	1500 mg/d ^a	4700 mg/d ^b
Basis for AI	To cover possible daily losses, provide adequate intakes of other nutrients, and maintain normal functions	Based on dietary intake levels should maintain lower blood pressure, reduce adverse effects of sodium chloride intake on blood pressure, reduce risk of recurrent kidney stones, and possibly decrease bone loss
Tolerable Upper Intake Level (UL)	2300 mg/d ^c	In healthy people, excess potassium above the AI is readily excreted in urine; therefore, a UL was not set
Basis for UL	Blood pressure. Difficult to precisely set AI because relationship between sodium intake and blood pressure is progressive and continuous, and other factors impact blood pressure (weight, exercise, potassium intake, dietary pattern, alcohol intake, and genetic)	No evidence that a high level of potassium from foods has adverse effects

^aAged 19 to 50 years, other AIs extrapolated based on median energy levels.
^bAged 19 to older than 70 years, AIs for aged 1 to 18 years extrapolated based on median energy levels.
^cBased on ages 19 to 50 years, ULs for ages 1–18 years extrapolated based on median energy levels.

new AHRQ review and Guiding Principles report, they are not limited to these in developing their conclusions. A 2013 IOM report examined designs, methodologies, and conclusions regarding dietary sodium and health outcomes in various at-risk populations, implications for population-based sodium reduction strategies, and research gaps and ways to address these.¹¹ This provides additional perspective on key questions (KQs).

WHAT THE LATEST SCIENCE SAYS REGARDING THE RELATIONSHIPS OF SODIUM AND POTASSIUM TO CHRONIC DISEASE

To prepare for the DRI sodium and potassium review, the AHRQ systematic evidence review on the relationships of sodium and potassium intakes to chronic disease was funded by the Department of Health and Human Services and the US Department of Agriculture.¹⁰ Commissioning such a systematic review has become a component of the DRI process.⁹ The Agency for Healthcare Research and Quality, through its Evidence-based Practice Centers, sponsors the development of systematic reviews to assist public- and private-sector organizations in their efforts to improve the quality of healthcare in the United States. Such reviews do not suggest or address the nature of reference intakes, but rather array the evidence in a fashion that allows the committee members to readily see the strength and nature of available evidence. Systematic reviews are key to evidence-based practice to identify

strengths and limitations from the available research studies. These reviews follow specified methodological guidelines to provide rigor and minimize bias. The sponsor provided a protocol for the sodium and potassium review, which was refined by the review team in consultation with a technical expert panel. The protocol was published in Prospero, a database for systematic review protocols. Preregistering protocols is recommended to minimize risk of bias. Almost 16 000 unique citations were reviewed, resulting in inclusion of 257 publications on 171 studies eligible for review. Summary tables were developed, the data analyzed, and the strength of evidence graded for conclusions. A draft report was published for peer and public review. The report was then revised with a final publication published in June 2018.

The purpose of this review was to lay out the evidence regarding the effects of dietary sodium and potassium intake on cardiovascular diseases (CVDs) and renal disease outcomes. The review focused on 8 KQs related to sodium and potassium intake, respectively, and their relationships to chronic disease, examining randomized controlled trials (RCTs) and epidemiologic data separately. Four of the KQs focused on results from RCTs and controlled clinical trials, whereas the other 4 KQs focused on prospective cohort studies. The questions focused on clinical trials evaluated effects, whereas those focusing on observational studies evaluated associations. Outcomes and strength of the evidence (SoE) was assessed on questions regarding sodium and potassium and their interrelationships with blood pressure, CVD, kidney disease, stroke, morbidity, and mortality in adults and children and various subpopulations.

Risk of bias of the included studies was assessed using published, standardized tools. These included the Cochrane risk of bias tool for RCTs and the Newcastle-Ottawa tool for risk of bias among observational studies. Other sources of bias considered were funding source and potential conflict of interest, potential for systematic error, and random error in sodium assessment.

Strength of the evidence (SoE) was assessed, considering study limitations, how well the outcome represented the true outcome of interest, consistency, degree of certainty around an estimate, and reporting bias. Levels of SoE were determined. In the case of this review, no conclusions received a high strength of evidence rating. Findings were at moderate or low levels of strength, or insufficient evidence was cited. When no evidence exists, an insufficient grade was assigned.

Table 3 provides the key messages summarizing the report findings. The report's overall conclusions were "reducing sodium intake, increasing potassium intake, and using potassium-containing salt substitutes in the diet significantly decrease blood pressure, particularly among those with hypertension. Limited evidence also suggests that sodium intake is associated with risk of all-cause mortality and that reducing sodium intake may decrease the risk of CVD morbidity and mortality." The RCTs provided the best evidence demonstrating the effect of decreasing dietary sodium intake on blood pressure reduction and therefore decrease in incidence of hypertension in adults. This aligns with the finding from observational studies that found higher sodium intakes were associated with greater risk of hypertension, although findings were deemed to be a low level of evidence.

All studies meeting the prespecified inclusion criteria were retained and evaluated. The authors noted that the conclusions were based mainly on data from the controlled intervention trials. The conclusions found to be of moderate strength of evidence were based on clinical trial results. Conclusions based on observational studies were rated at a low level of strength of evidence, consistent with the GRADE (Grading of Recommendations Assessment, Development, and Evaluation) approach that downgrades observational studies. The best evidence available was in adults, with generally limited evidence in subpopulations. Challenges in evaluating the data included study designs, which are often not developed to answer the KQs for the review. Limitations of the evidence base included nature of the populations studied, interventions/intakes, comparators, outcomes, timing and duration, setting, and study design.

While RCTs are considered the criterion or standard for establishing diet and health relationships, generally such studies are not feasible for evaluating chronic disease outcomes because of the time course required to develop chronic diseases and costs. Observational studies are useful

TABLE 3 Key Messages From the AHRQ Report "Sodium and Potassium Intake: Effects on Chronic Disease Outcomes and Risks"¹⁰

<ul style="list-style-type: none"> • Decreasing dietary sodium intake most likely reduces blood pressure in normotensive adults and more so in those with hypertension.
<ul style="list-style-type: none"> • Higher sodium intake may be associated with greater risk of developing hypertension.
<ul style="list-style-type: none"> • Use of potassium-containing salt substitutes in the diet to reduce sodium intake most likely reduces blood pressure in adults.
<ul style="list-style-type: none"> • Increasing potassium intake most likely decreases blood pressure in adults with hypertension.
<ul style="list-style-type: none"> • All-cause mortality may be associated with sodium intake.
<ul style="list-style-type: none"> • Reduced sodium intake may decrease the risk of combined CVD morbidity and mortality.

in this case, but limitations include high risk of bias, residual confounding, reliance on measurement error-prone self-report, and inconsistencies in outcomes. Evaluating sodium and potassium intakes is difficult, with the best methods involving multiple urinary assessments over 24 hours or more. Most of the prospective cohort studies reported single 24-hour urinary excretion measures, single or 2-day dietary recalls without 24-hour urinary excretion, estimated sodium excretion to assess status, or sodium intakes via food frequency questionnaires. Risk of bias was difficult to assess for many studies because of omission of many details of study design and omission of conflict of interest statements.

This comprehensive review provides a key summary on the status of research regarding sodium, potassium, and chronic disease. The specific questions asked, inclusion and exclusion criteria for studies, and study quality are key factors impacting conclusions and SoE. While this review will be an important piece for the DRI panel's consideration, the panel will be considering other evidence as well in establishing AIs and ULs, as well as potentially establishing EARs, if sufficient data are deemed available.

INCORPORATING CHRONIC DISEASE END POINTS INTO DRIS

Historically, nutrient intake recommendations developed by consensus committees of the IOM (and now the HMD) have been issued through DRIs. These are based on needs of healthy individuals and groups, by age and sex, and different life stages (eg, pregnancy). Such DRIs have been developed for nutrients identified to be essential and are

meant to ensure adequacy via prevention of deficiency diseases and to prevent toxicities.

Why consider chronic disease in developing DRIs? Chronic diseases are those that last longer than 6 months and are the major causes of morbidity and mortality in the United States and Canada. Fifty percent of adult Americans have a chronic disease, and 25% have 2 or more. Top chronic diseases include heart disease, cancer, lung diseases, Alzheimer disease, and diabetes mellitus type 2.

There is an emerging body of evidence suggesting that food components may play a role in reducing or increasing risk of chronic diseases, yet no framework existed for developing DRIs for chronic diseases. Thus, HMD convened a committee to develop such guiding principles.⁹ This report reviews conceptual and methodological challenges and recommends principles with justification to consider in developing chronic disease DRIs and responded to a prior expert committee publication, which identified methodological challenges and options for developing chronic disease DRIs.¹²

Key issues relevant to sodium and potassium regarding chronic disease DRIs include (1) measuring chronic disease outcomes, (2) intake-response relationships, and (3) judging the evidence for causality. Chronic diseases are complex with multiple risk factors, and outcome definitions are further complicated by subtypes. In the case of CVD, these include coronary artery disease, stroke, heart failure and its subtypes, arrhythmias, myocardial infarction, cardiac arrest, and fatal and nonfatal surgical procedure events.

Ideally, the best end point for chronic disease is the incidence of such a disease using acceptable diagnostic criteria or composite end points. However, qualified surrogate disease markers may also be used when a food or component and chronic disease relationship is causal. Qualified surrogate markers are those with a sufficient body of evidence to establish they are on the causal pathway to disease. Use of surrogate markers is more feasible for use in RCTs than chronic disease end points, due to cost, time, and logistical issues. Surrogate markers should be able to explain a substantial portion of the nutrient and chronic disease relationship and must be able to be validated analytically. Of relevance in setting sodium and potassium DRIs is blood pressure, which is qualified by the FDA as a surrogate marker for CVD.⁵

The Guiding Principles report notes that a quantitative intake-response relationship must exist. The nature of the causal relationship must be understood to develop a DRI. Several challenges were identified, including that the intake and response relationships are not always linear. Relative risks, not absolute, are typically presented. Because the intake-response relationship is continuous, the report recommended that the DRI might best be described as a range. Setting a range presents a key difference for chronic disease DRIs compared with those traditionally set for adequacy, which is

generally a single number. When a nutrient impacts the risk of more than 1 chronic disease, then DRIs could be developed for each.

The report established principles for judging the evidence toward causality. Expert teams are needed who will follow an established protocol for review of the totality of the evidence under consideration for the scientific question. The committee recommended use of the GRADE system to evaluate nutrient-chronic disease evidence. It is a widely used, transparent approach to grading quality and certainty of evidence and strength of recommendations.¹³

Certainty of the evidence is rated for each outcome across studies. Randomized controlled trials start with a presumption of a high rating, with observational studies having a lower rating, with other aspects of design increasing or decreasing their ratings. For RCTs, ratings are modified downward if there are study limitations, imprecision, inconsistency of results, and if publication bias is likely. For observational studies, ratings are modified upward if there is a large magnitude of effect, dose response is observed, and if confounders are likely to minimize the effect. The final rating for each outcome is rated “high,” “moderate,” or “low.” Using GRADE, the committee recommended that development of chronic disease DRIs be based on at least moderate certainty that a causal relationship exists as well as the existence of an intake-response relationship. The GRADE system is used by several bodies in evaluating evidence, including the World Health Organization. The AHRQ report team used a similar system in grading the evidence regarding sodium and potassium and chronic disease relationships. The GRADE system will provide a useful framework for judging the evidence and has not been used in setting prior DRIs. The GRADE system provides guidelines for moving from evidence to policy and clinical recommendations.

The sodium and potassium DRI committee is the first to have these guiding principles to use in evaluating the evidence toward setting DRIs for chronic disease. Chronic disease outcomes and surrogates need to be defined. Quality data will be needed for all risk factors. Measuring intake and response relationships will be critical, although this may be challenging because of difficulties in assessing dietary intakes of sodium and potassium. Also, not all intake-response relationships are linear, and much sodium intake is hard to quantify. The Guiding Principles report recommended retaining ULs based on traditional toxicity end points. If evidence shows that intake of a nutrient increases chronic disease risk at higher levels, then the relationship could be characterized as one where a lower intake would be beneficial. Care needs to be taken that the UL does not imply a “bright line,” which if crossed would lead directly to increased chronic disease risk. Dietary Reference Intakes for chronic disease should take the form of a range, rather than a single number. Currently, the sodium UL is based

on a chronic disease biomarker, blood pressure, as a risk of hypertension.

REDUCING SODIUM IN THE FOOD SUPPLY—PROGRESS AND FUTURE GOALS

In a number of instances, the food industry has made progress in reducing the sodium content of their foods. An unpublished member survey conducted by the Grocery Manufacturers Association showed that between 2008 and 2013, the sodium purchased by consumers in member products decreased by 16%. There were statistically significant decreases in all 9 of the relevant USDA What We Eat in America categories and decreases in 26 of 32 relevant subcategories. The overall decrease represents more than 100 mg less sodium purchased per consumer per day from Grocery Manufacturers Association member products over the 5-year period.¹⁴

Modeling projections from other sodium reduction initiatives signal the likelihood of significant reductions in intakes. Recently, an analysis using NHANES data modeled changes in US sodium intake from reducing sodium concentrations of commercially processed and prepared foods to meet voluntary standards established in North America.¹⁵ The potential impact on sodium intakes was assessed using the voluntary standards from New York's National Salt Reduction Initiative (NSRI) and Health Canada's benchmark recommendations. The modeling yielded projections of reductions in US population daily mean sodium intakes from 3417 mg to 698 mg by applying NSRI 2014 targets and to 615 mg by applying Health Canada's 2016 benchmarks. The proportion of adults 19 years or older who consume 2300 mg/d or greater would decline from 88% to 71% by applying NSRI targets and to 74% by applying Health Canada benchmarks.

Health Canada just released a report evaluating the food industry's efforts to meet the voluntary benchmark targets. Voluntary sodium reduction in processed foods between 2010 and 2016 decreased average daily sodium intake by 8% to 2760 mg/d. Although this indicates considerable progress, 58% of Canadians 1 year or older still exceed the 2300 mg/d goal.¹⁶

In 2016, the FDA issued draft guidance on voluntary sodium reduction targets for the food industry.¹⁷ The goal was to "... complement existing efforts by food manufacturers, restaurants, and food service operations to achieve these goals." It is meant to be a gradual process, with targets set for 2 and 10 years, envisioning a back-and-forth learning process. Draft sodium targets were set for 150 food categories. Participation is voluntary by the food industry, and progress will be assessed via monitoring the US food supply. The FDA recognizes the complexities of these goals and aims to work with food companies and restaurants to gradually adjust sodium levels in food. These voluntary guidelines

provide FDA with greater flexibility to adjust these targets as additional information becomes available and as the food supply evolves. Additionally, an upper bound level has been defined. The intent is to provide companies with the flexibility and time to innovate using emerging science on sodium reduction technologies. The targets took into consideration the many functions of sodium in food, including taste, texture, microbial safety, and stability. Naturally occurring sodium or salt individuals added to their food is not being considered.

The FDA issued draft guidance on voluntary sodium reduction targets for the food industry. The goal was to "... complement existing efforts by food manufacturers, restaurants, and food service operations to achieve these goals." It is intended to be a gradual process, with targets set for 2 and 10 years, with a back-and-forth learning process. Draft sodium targets were set for 150 food categories. Participation is voluntary by the food industry, and progress will be assessed via monitoring the US food supply.

To maximize impact, the FDA is especially encouraging adoption by those food manufacturers with products that make up a sizeable proportion of national sales by category and restaurant chains that are national and regional in scope. Table 4 provides an example of some targets for 5 snack food categories. The Figure is an example provided by the FDA that illustrates baseline values of precooked sausages and delineates the 2- and 10-year targets and mean content. Some products have already achieved the 2- and 10-year targets.

Based on estimates using NHANES data, if the food industry adjusts sodium levels in food to the FDA's targets, presumably the short-term (2-year) and long-term (10-year) targets would reduce sodium consumption to approximately 3000 and 2300 mg/d, respectively. The estimates

in intakes were derived from sodium content listed on product labels and considered market share of the various offerings per category.

Many food categories contribute to sodium intake, with no one category comprising more than 7% of intakes overall.

The FDA requested comments on the voluntary guidance, seeking input from the industry on challenges posed by sodium reduction targets and approach, given the many functions of sodium in foods. Over 200 comments were received, many addressing the complexities involved in implementing the guidelines. Clarification of the methodology used in deriving category targets was requested. It was recommended that some categories be adjusted. Given the technical challenges, the industry noted 2 years is quite short, as time is needed for development and application of new technologies, particularly to ensure food safety. Innovation takes time, resources, and collaboration. Also, a process to address marketplace shifts in product offerings is needed, given that purchase patterns evolve.

Challenges in sodium reduction remain. Table 5 provides a summary of industry approaches and factors relevant to reducing sodium, adapted from proceedings of a workshop on opportunities and challenges in sodium reduction.¹⁸ Sodium chloride (salt), the predominant source of added dietary sodium, serves many functions in foods. There is no perfect commercially viable alternative for salt. Salt helps to bring out the flavor in food, and there is a significant difference between using salt within a food compared with using it on the surface of a food. For example, in soup, salt brings out the savory flavor of chicken broth and increases the brightness of carrots. In breads, it

helps to provide texture and the golden color that we associate with freshly baked bread. Other sodium salts include bicarbonate (leavening in baking), ascorbate (vitamin C source), lactate and sorbate (preservation), monosodium glutamate (umami taste), and citrate (pH regulation). All sodium salts contribute to sodium content of a food.

With consumers, taste is king, and sodium chloride plays multiple roles in taste. Salt increases saltiness, suppresses sweetness and bitterness, builds umami, and may or may not affect sourness. When salt is reduced or removed, the balance of these tastes in a product is altered. As a result, creative flavorings and seasonings must be applied to rebalance the taste. Also, there are temporal aspects to salty taste, and substitutes need to deliver against initial impact, body and mouth feel, and lingering flavors. Solutions must address multiple sensory aspects. Given its many roles and unique clean flavor, there is no perfect substitute. Other substitutes such as potassium chloride often require use of other ingredients to help mask bitterness and astringency.

Thus, in developing salt replacements, there is no one magic bullet or single approach, and solutions must be customized. Answers vary both across and within categories and even within varieties of a product. Each recipe or formula needs to be individually handcrafted and tested for consumer acceptability, shelf life, and often for microbial stability. The entire process for a single product can easily take 3–4 years. To commercialize a new sodium-reduced product, safety and functional research is needed, along with prototype and pilot plant trials. Product safety and integrity must be ensured along with consumer acceptability.¹⁴ Changes in product sodium levels may greatly impact liking and purchase intent. Consumers often believe products reduced in sodium won't taste the same and may be reluctant to even try new products if they believe them to be disadvantaged from a taste standpoint.

Ingredient and product development efforts in sodium reduction are ongoing. Bitterness masking and taste enhancers are under development. Strides have been made with changing the physical structure of sodium compounds

TABLE 4 Examples of FDA Sodium Reduction Targets for 5 Snack Food Categories^a

Examples of Food Categories in Major Category "Snacks"	Baseline mg/100 g (pkg)	2-y Target (mg/100 g)	10-y Target (mg/100 g)	Upper Bound (mg/100 g) 2 y/10 y
Unflavored potato and vegetable chips	585	500	250	650/480
Flavored potato and vegetable chips	774	630	380	830/630
Unflavored grain chips	438	390	300	510/410
Flavored grain chips	674	590	450	750/610
Puffed corn snacks	1075	870	550	1190/900

^aModified from <https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM504014.pdf>.

Sample Category: Precooked Sausage

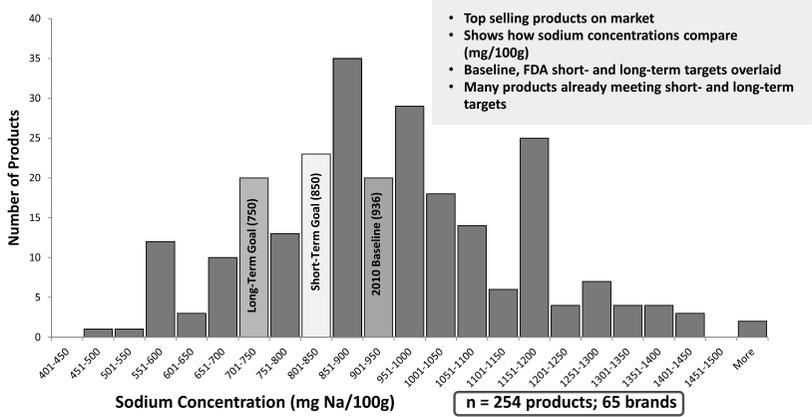


FIGURE. Example of FDA sodium reduction targets and status of a precooked sausage as a sample category. <https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/ucm505849.htm> at Download the Webinar Presentation Slides (PPTX: 4 MB). Accessed September 30, 2018.

and application methods (eg, on the surface only of chips vs dispersed throughout the products). Research is underway to better understand taste receptor biology, pharmacology, and genetics.

Today’s consumers are seeking “real” food. Transparency is key, and consumers want negatives removed and positives added. Reducing salt and sugar is desired, but equally important are actions such as removing artificial flavors and colors or increasing fruit, vegetables, and whole grains. In the era of “clean labels,” the presence of multiple ingredients to build back a taste profile can be inconsistent with consumers’ desires for “real” food made with a short list of recognizable ingredients. Names of ingredients that sound like chemicals are in disfavor. This is the case with potassium chloride, and a petition is under consideration by the FDA

to rename the ingredient “potassium salt,” which has tested more favorably with consumers.¹⁹

WHERE DO WE GO FROM HERE? REMAINING QUESTIONS

New DRIs for Sodium and Potassium

The DRI committee will need to determine if enough evidence now exists to establish EARs for sodium and potassium, or if AIs are to be retained and if they warrant changes. Intakes appear to have remained steady, much as they have historically and with different populations globally.⁴ Given the steady intakes over time, and the fact we know that sodium plays many roles in the body, are there metabolic drivers for intake of which we are unaware? Do

Industry Approach to Reducing Sodium	Factors Relevant to Reducing Sodium
1. Identify sodium target	• Controlling bacterial growth
2. Deconstruct food into components	• Controlling spoilage and shelf life
3. Identify sources of sodium in each ingredient	• Conducting appropriate process validation studies
4. Determine functional role of sodium-containing ingredients	• Finding appropriate salt substitutes
5. Reformulate and test prototype	• Maintaining product texture and color
6. Conduct sensory testing	• Promoting gluten development
7. Conduct processing validation for food safety	• Controlling and preserving flavor interactions
8. Conduct shelf life testing	• Containing costs

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we know enough to establish reliable AIs over a lifetime in today's populations?

Changes to the DRIs for sodium and potassium will impact nutrition policies in a number of ways. In an effort to reduce redundancies, questions regarding intakes of sodium and potassium and relationship to health are not included in the 2020–2025 Dietary Guidelines panel review. Instead, the guidelines will reference the existing guidance established by the new DRI review.²⁰ Feeding programs may be impacted, such as SNAP, WIC, the Child and Adult Care Feeding Program, and the National School Lunch Feeding Program. Health and nutrient content claims for foods may be affected.

Will the current DRI UL of 2300 mg/d be changed? This has implications for numerous policy recommendations, including the FDA category sodium reduction targets, and ultimately labeling of Daily Values. Tolerable Upper Intake Level considerations have been traditionally set to define a level that if exceeded may cause adverse health effects or toxicities. The Guiding Principles report recommended retaining ULs based on traditional toxicity end points. The current UL for sodium is based on blood pressure, a validated surrogate marker for hypertension. The Guiding Principles report suggests that chronic disease end points should not be used in setting ULs, and a range should be given. If DRIs are presented as a range, how will this impact policy translation and recommendations? While ranges reflect the uncertainty of the values, challenges remain in setting some nutrition policies, such as Daily Values, and as reference points in modeling sodium reduction targets for foods.

The AHRQ review found moderate strength of evidence for higher potassium intakes in reducing blood pressure. Approaches for encouraging intake of potassium require increased focus. Public health communications, consumer education, and improving consumer perception of potassium ingredients in the age of clean label, as well as improved claim language, will all be avenues to explore.

The AHRQ review found moderate strength of evidence for both lower sodium intakes and higher potassium intakes through supplements in significantly reducing blood pressure.

While chronic diseases are now being considered in developing DRIs, infectious diseases generally are not, although some qualify as chronic diseases. As we learn more on nutrient impacts on infectious diseases, as well as

impact on the microbiome and health outcomes, developing recommendations on intakes could be considered.

Sodium Reduction in Foods

Dr Scott Gottlieb, commissioner of the FDA, has identified sodium reduction as a key priority.²¹ Working with industry to adjust ingredient names to be more consumer-friendly, allowing more consumer-friendly nutrition and health claims and refining category sodium reduction targets and timelines are a few ways to support sodium reduction. Resources are required to monitor progress toward category target goals on a regular basis to understand changes that are occurring. The FDA will be working with other government agencies such as the US Department of Agriculture and the Centers for Disease Control and Prevention on these monitoring efforts and will be considering the numerous comments received on the sodium reduction category targets.

Sodium reduction in the food supply presents a natural experiment to determine if sodium intake will be reduced and if hypertension will be concomitantly reduced as well as other chronic diseases. Better methods for assessing intakes are needed. Also, limited evidence suggests that reducing sodium gradually can shift preference for lower amounts in the diet. These natural experiments are happening with reducing sodium in the food supply and hopefully intakes, which presents opportunities for tracking changes in preference. A basic understanding of how salt is detected and why sodium chloride tastes salty is lacking. A better understanding of these mechanisms will help in development of sodium replacers.

A better understanding of consumer desires, willingness to change, and productive means of engagement are needed. Consumers clearly desire wellness and nourishment for themselves and their families, but taste rules.²² Evidence indicates that consumers avoid products that are labeled low-sodium; therefore, stealth reduction strategies are commonly used. In the age of transparency, this presents a dilemma. Consumers make food choices based on multiple conscious and unconscious decisions. While surveys suggest that consumers may want to reduce sodium intakes, very few have the tools to track their intakes. Better tools are needed, along with an understanding that sodium is likely not a priority in what most consumers choose to eat.

As the food supply changes, this presents a natural experiment with children as well. Will children with reduced intakes have reduced preferences for salt throughout life? How will this relate to long-term health outcomes? A better understanding of developmental issues is needed, and little work has been done in this area.

A number of companies have explored approaches for reducing the sodium content of their foods, often with mixed results. Given that sodium has many roles, including for taste and recipe functionality, one size does not fit

all for reducing sodium in foods. Recipes need to be individually modified and consumer tested. Changes in product sodium levels greatly impact consumer liking and purchase intent. Taste remains the consumer priority. Consumers demand a say in selecting products that best meet their lifestyle needs. Aligning sodium reduction with consumer needs drives business success and the potential for better population health outcomes. With the introduction of new and modified products, opportunities exist to evolve overall product portfolios to lower sodium contents. The government and health professionals recognize the complexity of achieving meaningful reductions in population sodium intakes, and collaboration with industry is key to furthering success.

Acknowledgments

Christine Taylor, PhD, retired from the FDA, acted as moderator for this ASN 2018 session, and provided both an overview of the current state of affairs and an overview of the FDA's draft guidance for industry on voluntary sodium reduction goals. Dr Taylor served as study director of the 2010 IOM report "Strategies to Reduce Sodium Intake in the United States." Dr Taylor received travel funding from ILSI North America. Janet de Jesus, MS, RD, Nutrition Advisor at the Office of Disease Prevention and Health Promotion, formerly with NHLBI, led the interagency project to commission the AHRQ report evaluating the science regarding sodium, potassium, and their relationships to chronic disease. Marian L. Neuhouser, PhD, RD, full member and program head, Cancer Prevention Program, Fred Hutchinson Cancer Research Center, Seattle, Washington, reviewed the process and outcome for developing guidance for including chronic disease end points in DRI process, with implications specifically for sodium and potassium. Dr Neuhouser was a member of the National Academies of Sciences, Engineering, and Medicine panel developing this report. Joshua Anthony, PhD, MBA, vice president, Global Research and Development, Nutrition and Regulatory Affairs at the Campbell Soup Company, reviewed progress in sodium reduction by the food industry. Discussants included Gary Beauchamp, PhD, distinguished member of the Monell Chemical Senses Center and emeritus director and president, and Mary Christ-Erwin, global director, Food Beverage and Nutrition, at Porter Novelli, to bring in taste physiology considerations and consumer perspectives, respectively. Dr Beauchamp received travel funding from ILSI North America.

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The planners have disclosed no financial relationships related to this article.

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