

Issue Brief: Nutrients (Sodium, Phosphates and Potassium)

Sodium, phosphates and potassium are nutrients that may be naturally occurring in food or added due to the presence of certain ingredients. Sodium and phosphates are commonly added to processed foods, 1/ although both have been associated with negative health effects. Research has found that Americans consume excessive amounts of both nutrients and sodium in particular has been the focus of various reduction initiatives. In contrast, many Americans do not consume enough potassium. Accordingly, potassium is a nutrient of concern in the 2010 Dietary Guidelines for Americans. All three nutrients could be addressed in the 2015 Dietary Guidelines for Americans.

Legal Framework

Under section 409 of the Federal Food, Drug, and Cosmetic Act (FFDCA), a substance added to a food is a "food additive" for which FDA premarket approval is required *unless* the substance is generally recognized as safe (GRAS) for its intended use or qualifies for another statutory exemption. 2/ A determination that a substance is safe and appropriate for use in foods may be based either on (1) common use in food prior to 1958; or (2) a showing through scientific procedures that the substance is safe under the conditions of its intended use. 3/

In 1959, FDA issued regulations establishing substances it considered GRAS, including salt. (Most, but not all, sodium is added to food in the form of sodium chloride -- commonly known as "salt"). As there are many different additive forms of sodium, potassium, and phosphorus, each substance must be examined individually to determine whether it may legally be used in food because it is an approved food additive, has been affirmed as GRAS by FDA, or is GRAS through the self-affirmation process.

In addition, FDA's regulations govern the declaration of these three nutrients on food labels. First, all ingredients must be declared on packaged food labels. 4/ Thus, when ingredients that contain sodium, potassium, and phosphorus additives are added to food, they must be listed in the ingredient statement by an appropriate common or usual name such as salt, potassium chloride, or sodium tripolyphosphate. Further, in response to the Nutrition Labeling and Education Act (NLEA), FDA's regulations require the declaration of sodium in absolute amounts

1/ Phosphorus additives are commonly added to packaged foods as anticaking agents, to help preserve moisture or color, as stabilizers, leavening agents, and acidifiers, and also as flavor enhancers.

2/ 21 U.S.C. § 348.

3/ FFDCA § 201(s); 21 U.S.C. § 321(s).

4/ 21 C.F.R. § 101.4.

and as a percentage of the Daily Value (DV) in the Nutrition Facts Panel of a food label. ^{5/} In addition, due to the Patient Protection and Affordable Care Act of 2010, certain restaurants and similar retail food establishments must provide, upon request, written nutrition information, which includes sodium content, for standard menu items. Generally, potassium and phosphorus only need to be declared in the Nutrition Facts Panel when they are added as a nutrient supplement to the food or a claim is made about them on the label or in labeling. ^{6/} FDA has also established nutrient content claims when made about sodium, potassium, or phosphorus ^{7/} as well as health claims when made for sodium and potassium. ^{8/}

Although not a legal document governing the use of sodium, potassium, or phosphates, the 2010 Dietary Guidelines for Americans (DGA) represent federal nutrition policy and serve as the basis for federal food and nutrition education programs (including school meal programs). The 2010 DGA recommendations are to “reduce daily sodium intake to less than 2,300 milligrams (mg) and further reduce intake to 1,500 mg among persons who are 51 and older and those of any age who are African American or have hypertension, diabetes, or chronic kidney disease.” ^{9/} The 2010 DGA also recommend most Americans increase their consumption of potassium. Notably, dietary potassium can help blunt the adverse effects of sodium on blood pressure. The Adequate Intake (AI) for potassium for adults is 4,700 mg per day, but few Americans consume enough potassium. Thus, potassium is a nutrient of concern in the 2010 DGA. ^{10/}

Recent Developments

- In May 2013 report, the Institute of Medicine (IOM) Committee on the Consequences of Sodium Reduction in Populations issued a report concluding: (1) Current science does not support any benefit or harm from lowering sodium intakes below 2,300 mg/day; and, (2) The evidence on direct health outcomes does not support recommendations to lower sodium intake within population subgroups (those 51 and older and those of any age who are African American or have hypertension, diabetes, or chronic kidney disease) to or below 1,500 mg/day. ^{11/}
- Recent studies “extend the IOM report by identifying a specific range of sodium intake (2,645–4,945 mg) associated with the most favorable health outcomes,

^{5/} 21 C.F.R. § 101.9(c).

^{6/} *Id.*

^{7/} 21 C.F.R. §§ 101.13; 101.54; 101.61.

^{8/} 21 C.F.R. § 101.74; Food and Drug Administration, Health Claim Notification for Potassium Containing Foods (Oct. 31, 2000), <http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm073606.htm>.

^{9/} U.S. Department of Agriculture and U.S. Department of Health and Human Services, *Dietary Guidelines for Americans 2010* x (7th Ed. Dec. 2010) available at:

<http://www.health.gov/dietaryguidelines/dga2010/DietaryGuidelines2010.pdf>.

^{10/} *Id.* at 40.

^{11/} Institute of Medicine (IOM), *Sodium Intake in Populations: Assessment of Evidence* (May 2013), <http://www.iom.edu/Reports/2013/Sodium-Intake-in-Populations-assessment-of-Evidence.aspx>.

within which variation in sodium intake is not associated with variation in mortality.” [12/](#) [13/](#) [14/](#) [15/](#)

- In June 2013, USDA’s Food and Nutrition Service (FNS) issued an interim final rule on foods sold in schools other than those provided under the National School Lunch Program (NSLP) and School Breakfast Program (SBP) (so-called “competitive foods”). These standards, which went into effect July 1, 2014, include restrictions on the sodium content of competitive foods. [16/](#) Likewise, the NSLP and SBP also restrict the sodium content of foods in those programs, by providing a daily amount that meals must not exceed. [17/](#)
- In November 2013, the European Food Safety Authority (EFSA), following a request from the European Commission, reviewed a scientific article concerning the safety of phosphates. The article suggested an association between a high intake of phosphates as food additives and increased cardiovascular risk in the general population. EFSA concluded that studies investigating an association between dietary intake of phosphorus and serum concentrations are inconclusive. EFSA recommended that the reevaluation of phosphoric acid and phosphates, as well as polyphosphates for use as food additives, take place as planned (according to Regulation (EC) No 257/2010, by December 31, 2018), with high-priority.

Also in November 2013, a study published in the *American Journal of Clinical Nutrition* found that high phosphorus intake was associated with increased mortality in healthy adults. The study found that more than one third of Americans reported consuming more than 1400mg of phosphorus a day (twice the Recommended Daily Allowance), which was associated with an increase in all-cause mortality.

[12/](#) Graudal N, G Jurgens, B Baslund, and MH Alderman. Compared with usual sodium intake, low- and excessive- sodium diets are associated with increased mortality: a meta-analysis. *American Journal of Hypertension*. 2014; 1 – 9.

[13/](#) Prospective Urban Rural Epidemiology (PURE) investigation. Mente A., M.J. O’Donnell, S. Rangarajan, M.J. McQueen, P. Poirier, A. Wielgosz, H. Morrison, W. Li, X. Wang, C. Di, P. Mony, A. Devanath, A. Rosengren, A. Oguz, K. Zatonska, A.H. Yusufali, P. Lopez-Jaramillo, A. Avezum, N. Ismail, F. Lanas, T. Puoane, R. Diaz, R. Kelishadi, R. Iqbal, R. Yusuf, J. Chifamba, R. Khatib, K. Teo, and S. Yusuf. Association of Urinary Sodium and Potassium Excretion with Blood Pressure. *The New England Journal of Medicine*. 2014; 371 (7): 601-611. Prospective Urban Rural Epidemiology (PURE) investigation. O’Donnell M., A. Mente, S. Rangarajan, M.J. McQueen, X. Wang, L. Liu, H. Yan, S.-F. Lee, P. Mony, A. Devanath, A. Rosengren, P. Lopez-Jaramillo, R. Diaz, A. Avezum, F. Lanas, K. Yusoff, R. Iqbal, R. Ilow, N. Mohammadifard, S. Gulec, A.H. Yusufali, L. Kruger, R. Yusuf, J. Chifamba, C. Kabali, G. Dagenais, S.A. Lear, K. Teo, and S. Yusuf. Urinary Sodium and Potassium Excretion, Mortality, and Cardiovascular Events. *The New England Journal of Medicine*. 2014; 371 (7): 612-623.

[14/](#) Prospective Urban Rural Epidemiology (PURE) investigation. O’Donnell M., A. Mente, S. Rangarajan, M.J. McQueen, X. Wang, L. Liu, H. Yan, S.-F. Lee, P. Mony, A. Devanath, A. Rosengren, P. Lopez-Jaramillo, R. Diaz, A. Avezum, F. Lanas, K. Yusoff, R. Iqbal, R. Ilow, N. Mohammadifard, S. Gulec, A.H. Yusufali, L. Kruger, R. Yusuf, J. Chifamba, C. Kabali, G. Dagenais, S.A. Lear, K. Teo, and S. Yusuf. Urinary Sodium and Potassium Excretion, Mortality, and Cardiovascular Events. *The New England Journal of Medicine*. 2014; 371 (7): 612-623.

[15/](#) Oparil S. Low Sodium Intake — Cardiovascular Health Benefit or Risk? *The New England Journal of Medicine*. 2014; 371 (7): 677-679.

[16/](#) Snacks side dishes may not contain more than 230 mg of sodium until June 30, 2016; then the limit is reduced to 200 mg. Entrees may not contain more than 480 mg of sodium. Note that states and local education agencies can implement stronger nutrition standards for competitive foods.

[17/](#) For the 2014-2015 school year, breakfast meals are not to contain more than 540-640 mg of sodium, depending on student grade level. Lunches are not to contain more than 1230-1420 mg of sodium, depending on grade level.

Issues to Watch

- **FDA's Approach to Sodium Reduction.** FDA has identified "advance and complete a plan for broad gradual reduction of added sodium in the food supply" as one of its priorities for 2013-2014. For sodium, FDA might seek voluntary reductions (as New York City has tried), possibly in conjunction with lowering the Daily Value. More dramatically, FDA could propose revoking or otherwise limiting sodium's generally recognized as safe (GRAS) status as leverage for negotiations with industry.
- **USDA sodium monitoring efforts.** USDA Agricultural Research Service (ARS) Nutrient Data Laboratory (NDL) "[Monitoring Sodium and Selected Nutrients in Foods](#)" project – leveraging National Dietary Surveillance Program, Sentinel Foods in What We Eat in America (WWEIA) Food Categories (NND-SR-R26) - is expected to be completed by July 15, 2015. [Updates](#) are to be disseminated in successive releases of the National Nutrient Database for Standard Reference (SR).
- **Dietary Guidelines for Americans.** The next revisions to the Dietary Guidelines for Americans are expected in 2015. The Dietary Guidelines Advisory Committee (DGAC) is currently meeting to discuss revisions to the DGA. Sodium recommendations are expected to be a key issue, particularly in light of the IOM report's conclusions. Furthermore, the DGA could continue to identify potassium as a nutrient of concern. Phosphates thus far have not received as much public attention as other nutrients associated with negative health affects (e.g., sodium and sugar).
- **Voluntary Reduction Initiatives.** The success of food manufacturers at voluntarily reducing sodium in manufactured foods is likely to remain a key issue in determining future federal initiatives concerning this nutrient.
- **FDA's Proposal to Revoke the GRAS Status of Partially Hydrogenated Oils (PHOs).** How FDA decides to approach PHO's may influence the agency's course of action regarding sodium. The Center for Science in the Public Interest (CSPI) filed a petition with FDA in 2005 requesting FDA amend its regulations to revoke the GRAS status of salt and reclassify it as a food additive. In addition to other requests, CSPI also wants FDA to set ceilings for the amount of salt allowed in processed foods.
- **Revisions to the Nutrition Facts Panel.** FDA's two proposed rules on revising the Nutrition Facts Panel and Reference Amounts Customarily Consumed were recently published. These rules may revise the Daily Value for sodium (currently at 2400 mg) (and potassium and phosphorus) and may also change the way sodium content and other nutrients are declared on the NFP by, among other things, changing the way a food's serving size is determined.

International Perspective

- **European Union (EU):** Under current law, the addition of sodium, potassium or phosphates to a food triggers the need to provide nutrition labeling, including information on the specific nutrient(s) added. Nutrition labeling is also required when a nutrition or health claim is made. Starting in 2016, nutrition labeling will be mandatory regardless of whether nutrients are added to the food or a claim is made. Sodium, potassium, and phosphates can only be added to foods if they are listed in the EU Added Nutrients Regulation and when in the permitted chemical form. ^{18/} No maximum levels for the intake of vitamins and minerals have been adopted yet at the EU level. Some EU Member States have decided, however, to establish maximum levels under their national legislation. Minimum levels, which are referred to as "significant amounts," constitute 15% of the Recommended Daily Allowance (RDA) for a given vitamin or mineral established in Annex I to Directive 496/90/EEC on nutrition labelling for foodstuffs (the "EU Nutrition Labelling Directive"). ^{19/} EFSA is currently reviewing all food additives by the end of 2018, according to Regulation (EC) No 257/2010. Several additives containing sodium, phosphates, and potassium are a high priority for review, some of which will be reviewed under a shorter time frame.
- **Canada:** [Health Canada proposed changes to the nutrition information on food labels](#) to include new guidelines to help make serving sizes – based on reference amounts - declared in the Nutrition Facts table more consistent among similar food products; changes to the list of nutrients and corresponding daily values (DV) to be declared in the Nutrition Facts table and the way sugar is labeled; and, formatting changes to the Nutrition Facts table and the list of ingredients, and the proposal to create an optional information box highlighting the presence of certain bioactive components, such as caffeine. Health Canada has published a series of fact sheets on the proposed changes to the [NFP format](#), [sugar labeling](#) and [serving size guidelines](#). Relative to sodium, Health Canada published its 2010 Sodium Reduction Strategy for Canada with an interim goal of reducing daily sodium intake to 2,300 mg by 2016. ^{20/}
- **United Kingdom (UK):** The same rules that apply in the EU to sodium, phosphates, and potassium have been adopted and apply in the UK. The Food Standards Agency (FSA) has twice (in 2006 and revised downward in 2009) set voluntary sodium targets for over 80 categories of food. Revised

^{18/} See <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2006R1925:20111205:EN:PDF>.

^{19/} See <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1990L0496:20081211:EN:PDF>

^{20/} See http://www.hc-sc.gc.ca/fn-an/alt_formats/pdf/nutrition/sodium/strateg/reduct-strat-eng.pdf. The Strategy sets an interim goal of reducing daily sodium intake from 3400 mg to 2300 mg by the year 2016. The multi-staged strategy includes recommendations in the areas of education, voluntary reduction of sodium levels in processed food products and foods sold in food service establishments, research, and monitoring and evaluation.

sodium targets may be forthcoming as part of the government's Salt Strategy, announced in March 2013. 21/

- **Codex and World Health Organization (WHO):** In 2013, Codex established a sodium nutrient reference value (NRV) for risks associated with diet-related non-communicable diseases (NCD) at 2,000 mg, 22/ based on the [2012 WHO Guidelines on Sodium intake for adults and children](#) which was simultaneously released with the 2012 WHO Guidelines on Potassium intake for adults and children. 23/ At the upcoming 36th Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU), an NRV-NCD for potassium will likely be established at 3,500 mg. 24/ Additionally, at its 76th meeting, the Joint WHO/FAO Expert Committee on Food Additives and Contaminants (JECFA) emphasized the need for total dietary exposure assessment to phosphorus. 25/ Finally, the 66th World Health Assembly (WHA) released its 2013-2020 Global Action Plan for the Prevention and Control of NCDs to promote effective nutrition labeling for pre-packaged foods that encourages a healthy diet. 26/

AFFI Action Items

- AFFI submitted comments to the 2015 Dietary Guidelines for Americans (DGA) Advisory Committee regarding sodium September 2013 sharing its views on the importance of basing any dietary guidelines for sodium upon sound science. In particular, we urged the DGA Advisory Committee to carefully consider the Institute of Medicine's (IOM's) recent report on sodium reduction.
- AFFI submitted comments to FNS regarding the standards for competitive foods. Among other concerns, AFFI urged FNS to modify the sodium requirements to ensure consistency with the reimbursable food standards. In addition, AFFI explained that the criterion allowing foods containing 10% daily value of a nutrient of public health concern (of which potassium is one) to qualify as competitive foods should not be phased out in 2016. AFFI also requested a two year delay in implementation.

21/ See <https://www.gov.uk/government/news/government-drive-to-help-cut-salt-consumption-by-a-quarter>.

22/ Codex Guidelines on Nutrition Labeling (CAC/GL 2-1985) -

http://www.codexalimentarius.org/download/standards/34/CXG_002e.pdf. An NRV of 2,000 mg was based on based on "convincing evidence" for a relationship with NCD risk as defined in the report *Diet, Nutrition and the Prevention of Chronic Diseases*. WHO Technical Report Series 916. WHO, 2003. The updated WHO guideline on sodium intake for adults and children (WHO 2012) further supports the selection of sodium.

23/ See http://apps.who.int/iris/bitstream/10665/77986/1/9789241504829_eng.pdf?ua=1. This guideline provides the first global, evidence-informed recommendations on the consumption of potassium to reduce NCDs in most adults and children which WHO had developed.

24/ See ftp://ftp.fao.org/codex/meetings/CCNFSDU/ccnfsdu36/nf36_08e.pdf.

25/ Maximum tolerable daily intake (MTDI) of 70 mg/kg body weight (bw) for phosphate salts, expressed as phosphorus. "The Committee emphasized that in evaluating individual phosphate-containing food additives, there is a need for assessment of total dietary exposure to phosphorus."

http://www.fao.org/fileadmin/user_upload/agns/pdf/76th_JECFA_summary_report.pdf

26/ See http://apps.who.int/iris/bitstream/10665/94384/1/9789241506236_eng.pdf?ua=1;
http://apps.who.int/gb/ebwha/pdf_files/WHA66/A66_R10-en.pdf?ua=1.

- AFFI submitted additional comments May 2014 in response to FDA's and USDA Food Safety and Inspection Service's 2011 request for information concerning approaches to reducing sodium consumption. Comments highlighted key outcomes – specifically, the distribution range of sodium intake that affords a favorable health outcome - resulting from ongoing research, analyses and reviews on this topic since the close of the comment period early 2012. With respect to sodium in particular, AFFI will continue to stress that any federal sodium reduction initiatives be based upon science and take a flexible and gradual approach to sodium reduction, taking into account the complex role of sodium in the food supply, as well as industry capabilities and consumer palates. AFFI's lead role in response to FDA's tentative determination that PHO's are no longer GRAS will give it insight into potential avenues the agency might take with respect to sodium and potential industry responses.
- AFFI will continue to monitor FDA and FSIS developments regarding all three nutrients.

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