The Use of an Alternate Name for Potassium Chloride in Food Labeling: Guidance for Industry

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The Use of an Alternate Name for Potassium Chloride in Food Labeling: Guidance for Industry[1]

This guidance represents the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

The purpose of this guidance is to advise food manufacturers of our intent to exercise enforcement discretion for declaration of the name "potassium salt" in the ingredient statement on food labels as an alternative to the common or usual name "potassium chloride."

FDA intends to exercise this enforcement discretion to provide industry with greater flexibility when labeling their food products, including those that are formulated to reduce sodium content. This enforcement discretion may result in manufacturers using potassium chloride as a substitute ingredient for some sodium chloride and may lead to reduced sodium intake.

This guidance is consistent with FDA's Nutrition Innovation Strategy to reduce the burden of chronic disease in the United States through improved nutrition, by empowering consumers with information, and supporting and fostering industry innovation in developing and promoting healthfulness of food options.[2,3] This guidance is also consistent with FDA's previous activities to encourage manufacturers to reduce the sodium levels in food products in the interest of public health.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe our current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidances means that something is suggested or recommended, but not required.

[1] This guidance has been prepared by the Office of Nutrition and Food Labeling in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.
[2] FDA Nutrition Innovation Strategy. March 2018. https://www.fda.gov/Food/LabelingNutrition/ucm602651.htm.
[3] Healthy Innovation, Safer Families: FDA's 2018 Strategic Policy Roadmap: https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM592001.pdf (pg. 15).

II. Background

Under section 403(i)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the label of food fabricated from two or more ingredients must bear the common or usual name of each ingredient.[4] A common or usual name is the name by which an article is known to the American public. Common or usual names are generally established by common usage, though in some cases they may be established by regulation pursuant to sections 403(a)(1), 403(i), and 701(a) of the FD&C Act. See 21 CFR 102.5(d).[5]

"Salt" is the common or usual name of sodium chloride. See 21 CFR 101.22(h)(4). Salt is defined as "a usually whitish crystalline solid, chiefly sodium chloride, used extensively in ground or granulated form as a food seasoning and preservative."[6] Thus, in the context of food, the name "salt" specifically refers to sodium chloride. A salt is also defined as "an ionic chemical compound formed by replacing all or part of the hydrogen ions of an acid with metal ions or other cations."[7] Both sodium chloride and potassium chloride, in addition to other potassium- and sodium-containing food ingredients (e.g. potassium citrate, sodium lactate), are salts within this definition. Although potassium chloride is a type of salt, the common or usual name for this ingredient is "potassium chloride," as established by longstanding common usage.

Americans consume on average 3,400 milligrams (mg) of sodium per day, nearly 50 percent more than the 2,300 mg/day limit recommended by Federal guidelines (Ref. 1). Excess sodium intake increases risk for hypertension (Refs. 2, 3, 4, 5), a leading cause of heart disease and stroke, which in 2018 were the first and fifth leading causes of mortality in the United States, respectively (Ref. 6).

Over 70 percent of sodium consumed comes from processed and prepared foods (Ref. 7). Food manufacturers wishing to reduce sodium chloride in their products sometimes use substitute ingredients that provide similar taste and other technical functions of sodium chloride in foods. One such substitute ingredient that can be used across a number of food categories is potassium chloride (Ref. 8, 9, 10, 11). Potassium chloride is also recognized as a substitute for sodium chloride by certain Codex standards (Ref. 12). Potassium chloride is generally recognized as safe (GRAS) as a food ingredient when used under the conditions specified in 21 CFR 184.1622. These conditions include use as a flavor enhancer, flavoring agent, nutrient supplement, pH control agent, stabilizer, and thickener. From a food technology perspective, sodium chloride and potassium chloride to a certain extent have similar taste and functions (e.g. preservation, moisture retention) (Ref. 13, 14, 15). In most instances, potassium chloride is used as a partial substitute for sodium chloride.

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[4] See also 21 CFR 101.4(a)(1).
[5] When establishing a common or usual name by regulation, FDA considers the principles under 21 CFR 102.5(a)-(c).
[6] The American Heritage Dictionary definition for "salt." Available online: https://www.ahdictionary.com/word/search.html?q=salt
[7] *Id.*

From a nutrition and public health perspective, the substitution of potassium chloride for sodium chloride is advantageous due to the over-consumption of sodium and under-consumption of potassium at the population level compared to federal recommendations.[8] Increased potassium intake is associated with improved blood pressure control (Ref. 16). The 2015-2020 *Dietary Guidelines for Americans* states that potassium is a "nutrient of public health concern" (Ref. 1). The average daily potassium intake in the U.S. is approximately 3,000 mg/day for men and 2,300 mg/day for women (Ref. 17), but the Adequate Intake of potassium is 3,400 mg/day for men and 2,600 mg/day for women (Ref. 2). Potassium is therefore under-consumed in the U.S.

III. Guidance

Potassium chloride, in some instances, can be used as a partial substitute for sodium chloride in food processing and manufacturing, and this use may help to reduce sodium in food. FDA has considered whether declaration of alternate names for potassium chloride may signal to consumers that a potassium-based salt has been used as a substitute for sodium chloride in food. Such information may help facilitate consumers' choices to decrease their sodium consumption.

The alternate name "potassium salt" may help consumers understand the identity of potassium chloride and its use as a salt substitute. The term "salt" conveys that the ingredient is a salt, similar to sodium chloride (declared as "salt"). The term "potassium" identifies the ingredient as containing potassium. Because potassium chloride does not appear to be generally known to consumers as a food ingredient (Ref. 18), FDA considers it unlikely that consumers would be confused by declaration of "potassium salt" when potassium chloride is used as an ingredient, or would believe that a different ingredient is present. Further, because of the addition of the word "potassium" before "salt," FDA believes that consumers are unlikely to confuse the ingredient with sodium chloride. Inclusion of "potassium" in "potassium salt" should indicate to consumers that the ingredient is distinct from the ingredient commonly known and declared as "salt." Therefore, it is unlikely that the alternate name will mislead consumers.

In summary, FDA considers this approach appropriate in this specific circumstance due to: the important public health benefits for the U.S. population that could result from reduced sodium and increased potassium intake; the recognition that potassium chloride can substitute for sodium chloride in a variety of food manufacturing applications across a number of food categories; and the unlikelihood that the alternate name will mislead consumers.

Thus, we consider it appropriate to exercise enforcement discretion for the declaration "potassium salt" in the place of "potassium chloride" in the ingredient statement of food labels when potassium chloride is used as an ingredient in the food.

[8] Information regarding the potassium content of a product is available to consumers via the ingredient listing on food packages. In addition, the updated Nutrition Facts label final rule issued by FDA in 2016 (81 FR 33742) and required on most food packages by January 2020, requires a declaration of potassium on the Nutrition Facts label – both the absolute amount per serving as well as the percent Daily Value.

IV. Paperwork Reduction Act of 1995

This guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521) is not required.

However, this guidance refers to previously approved FDA collections of information. These collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 101 have been approved under OMB control number 0910-0381.

V. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 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 https://www.regulations.gov. References without asterisks are not on public display at https://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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