



Portfolio Media, Inc. | 860 Broadway, 6th Floor | New York, NY 10003 | www.law360.com
Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

Potassium Chloride Should Be Potassium Salt On Food Labels

Law360, New York (June 29, 2016, 3:33 PM ET) -- On June 27, 2016, NuTek Food Science LLC filed a citizen petition with the U.S. Food and Drug Administration that, if granted, will provide great benefits to consumers by helping the FDA and the food industry in their efforts to enhance the nutritional profiles of foods and ultimately advance the health and wellness of the U.S. population. Specifically, the citizen petition requests "the commissioner to issue guidance recognizing 'potassium salt' as an additional common or usual name for potassium chloride as that ingredient is defined in 21 C.F.R. § 184.1622" (the "potassium salt petition" or the "petition").



Ashlee M. Knuckey

Although potassium chloride has been an ingredient in food for decades, there is consumer confusion over what it is. Consumers often misassociate the "chloride" element with chlorine or other chemicals. The labeling change proposed by the petition will provide clarity and consumer acceptance of potassium chloride, which will in turn help further the dietary goals articulated by the FDA — to lower sodium and increase potassium consumption.

Potassium Chloride (Potassium Salt) and Its Relation to Sodium Chloride (Salt)

Potassium, sodium and chloride are all naturally occurring elements that can be found on the periodic table and are essential to human health. Both potassium chloride (KCl) and sodium chloride (NaCl) are naturally occurring salts (ionic compounds made up of two groups of oppositely charged ions), and therefore play a similar role in food in terms of food safety, functionality and sensory effects:

- *Sodium chloride* is defined by the FDA, labeled on foods and commonly known to consumers simply as "salt." Sodium chloride (salt) is the most common source of sodium in the diet. Furthermore, under the current FDA labeling laws, consumers only see "salt" and not "chloride" on food labels containing sodium chloride (salt).
- *Potassium chloride*, on the other hand, is currently required to be labeled specifically as "potassium chloride" on food packaging — though health and consumer groups, scientists and the food industry commonly refer to it as potassium salt. Generally, it is used for two main purposes in food: (1) to replace a portion of the sodium chloride (salt) in order to replicate sodium chloride's taste, preservation and functional properties, and (2) to enhance the amount of potassium — an essential and widely underconsumed nutrient — contained in food products.

The FDA's Sodium Reduction Goals

Through both the FDA's new Food Labeling: Revision of the Nutrition and Supplement Facts Labels

final rule and draft guidance setting voluntary sodium reduction goals, issued on May 27, 2016 and June 1, 2016, respectively, the FDA recommends that Americans limit their total sodium consumption to 2,300 milligrams per day. Currently, however, the average sodium intake is approximately 3,400 milligrams per day, which is about 48 percent over the recommended upper limit.

Both the FDA and the Centers for Disease Control and Prevention recognize extensive research showing that decreasing sodium intake is expected to reduce the rate of hypertension (often referred to as high blood pressure). Hypertension is a major risk factor for both heart disease and stroke, which are ranked as the first and fifth leading causes of death in the United States. Today, approximately 75 percent of Americans' total sodium intake comes from processed and commercially prepared foods. For this reason, the FDA has recently issued Draft Sodium Reduction Guidance, proposing short-term (two year) and more ambitious long-term (10 year) sodium reduction targets for 150 categories of processed and restaurant foods.

Given the essential role of sodium chloride (salt) in food for microbial safety, stability and other functions (such as taste), substantive sodium chloride (salt) reduction can be a significant challenge for many food products. Simply removing sodium chloride (salt) from the food is not a realistic option in many instances. Instead, sodium chloride (salt) can only be removed or reduced to certain levels before the attributes of taste, functionality and food safety are adversely affected. Beyond these modest levels of sodium chloride (salt) reduction, a replacement salt is required to replicate these critical attributes. Potassium chloride has been used for this specific purpose for decades within the global food system, and is found in thousands of products within the U.S. food system.

The FDA's Goals to Increase Potassium

The FDA's stance on potassium in the Nutrition Labeling Rule is a natural complement and counterbalance to these sodium concerns. Specifically, the FDA recognizes that potassium helps to lower blood pressure and, when underconsumed, is associated with an increased risk of chronic diseases. According to the rule, potassium is a nutrient of public health concern because the majority of Americans substantively underconsume potassium in their diets. The FDA recently established a reference daily intake (RDI) for potassium of 4,700 milligrams per day. Today, the average American consumes 2,640 milligrams of potassium per day, representing a 2,060 milligram per day (44 percent) shortfall vs. the RDI.

The FDA explains that the 4,700 milligram per day level has been established to help maintain blood pressure, reduce the adverse effects of sodium chloride intake on blood pressure and reduce the risk of recurrent kidney stones. In addition, the rule now requires food manufacturers to list the quantitative amount of potassium by weight and percent of the RDI within the Nutrition Facts Panel in order to assist consumers in maintaining healthy dietary practices.

Confusion Over Potassium Chloride (Potassium Salt)

As explained above, the FDA has stated that Americans need to decrease their sodium intake and increase their potassium intake. The potassium salt petition also cites emerging research suggesting that the dietary sodium-to-potassium (Na:K) ratio is more strongly associated with an increased risk of hypertension and cardiovascular disease-related mortality than the risk associated from either sodium or potassium alone. However, the simple removal of sodium chloride (salt) alone will not work in many instances, and all or a portion of it must be replaced. This replacement is most commonly accomplished through the addition of potassium chloride (potassium salt).

But consumers may avoid food products that list potassium chloride as an ingredient, simply due to the term "chloride." Specifically, the petition cites consumer research showing that those surveyed appear to be more "concerned" about ingredients that list chloride in their name — stating that "chloride sounds unsafe" or "is too close to chlorine and chemical sounding."

Also, according to the petition's consumer research, consumers were asked whether they preferred the name "potassium chloride" or "potassium salt." More than 2-to-1, those surveyed preferred the name potassium salt — finding potassium salt to sound "more appetizing," "less

processed," "healthier" and "safer to consume."

The obvious concern is that consumers may choose a product that is higher in sodium chloride (salt) and devoid of potassium chloride (potassium salt), simply because it contains the term "salt" and not the term "chloride." Some also worry that, as a result, food manufacturers may remove potassium chloride and replace it with "salt" (sodium chloride) in order to avoid using "chloride" on a label. Such actions would further increase sodium content and decrease potassium content in foods — reversing past progress on sodium reduction and potassium enrichment. The ultimate result would be detrimental to nutritional profiles of foods and the overall health of the U.S. population.

The Potassium Salt Solution

The petition articulates that using "potassium salt" as the common or usual name for potassium chloride "more closely reflects reasonable consumer expectations of the ingredient and more accurately describes the basic nature of the ingredient and its chemical properties," as required by FDA regulations. The petition further explains that allowing entities to voluntarily label potassium chloride as potassium salt will improve consumer understanding and acceptance of potassium chloride, and allow the food industry to accelerate the process of decreasing sodium chloride (salt) and increasing potassium chloride (potassium salt) in food products.

To help solve these issues, the potassium salt petition requests that the FDA "issue guidance (a) recognizing 'potassium salt' as an additional common or usual name for potassium chloride and (b) advising that an ingredient meeting the specifications for and uses of potassium chloride as set forth in 21 C.F.R. § 184.1622 may be labeled as 'potassium salt.'"

On June 28, 2016, the Division of Dockets Management acknowledged receipt of the petition and posted it under docket number FDA-2016-P-1826. The FDA is accepting comments on the petition here.

—By Ashlee M. Knuckey, Locke Lord LLP

DISCLAIMER: Ashlee Knuckey assisted NuTek in the drafting and submission of the potassium salt petition.

Ashlee Knuckey is an associate in Locke Lord's Chicago office.

The opinions expressed are those of the author(s) and do not necessarily reflect the views of the firm, its clients, or Portfolio Media Inc., or any of its or their respective affiliates. This article is for general information purposes and is not intended to be and should not be taken as legal advice.

All Content © 2003-2016, Portfolio Media, Inc.