



ConAgra Foods, Inc.
Suite 950
1627 I Street, NW
Washington, D.C. 20006

TEL: 202-223-5115
FAX: 202-223-5118

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Brent A. Baglien
*Vice President
Government Affairs*

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket numbers 91N-304H and 96P-0500 - Food Labeling; Nutrient Content Claims, Definitions of Sodium Levels For The Term "HEALTHY"

With this letter and attachment, ConAgra Foods submits additional information to the above dockets. The information provided discusses the increased levels of sodium and sodium compounds in foods to meet the new U.S. Department of Agriculture (USDA) goals to enhance food safety by suppressing microbial pathogen growth. The document also reviews the goals and objectives of the recently released report of the Dietary Guidelines Committee and outlines the consistencies between those objectives and the consumer and marketplace experiences with the ConAgra Foods product line "Healthy Choice".

Sincerely,

Brent A. Baglien

96P-0500

SUP 2

Necessity for Maintaining Tier 1 Sodium Level Requirement for Healthy Claims on Meat and Poultry Products to Achieve Food Safety, Consumer Acceptability and Dietary Guidelines

November 30, 2004

Introduction

Sodium and sodium containing compounds are used to formulate safe, organoleptically and consumer acceptable products. With recent changes in food safety requirements, the role of sodium containing compounds as food safety interventions have increased and are expected to expand in usage by food manufacturers, because, despite ongoing research, viable sodium substitutes are simply unavailable in the marketplace.

If the food industry is required to reduce sodium levels on products that already contain greatly reduced levels of sodium, the marketplace, and ultimately consumers, will lose valuable options for safe and nutritionally beneficial foods. The Healthy Choice brand provides consumers a safe product that meets the recommendations made by the Dietary Guidelines Advisory Committee for the Dietary Guidelines for Americans for 2005. Adopting unworkable and unrealistically restrictive sodium levels in products labeled "healthy" has already had a detrimental effect of greatly reducing the number of "healthy" labeled products available to consumers.

Background

Developing a successful food product requires a balance of several components in order to ensure food safety, nutrition, product stability, great taste and pleasing appearance. These components include complex ingredients, and choosing the right compounds often depends on cooking and processing technologies, temperature states, and the end use of the product. For processed meat and poultry products, food scientists long ago realized that certain additives, such as chloride-, nitrite-, lactate- and diacetate-containing compounds (salts) required a stabilizing, food grade "carrier" (positive) ion in order to achieve the desired functionality of the other food components. As discussed below, sodium is the most suitable food grade, positive ion for stabilizing these additives. Consequently, if a food company were required to reduce the sodium in its meat formulations, then a critical characteristic of the final product, such as texture, flavor, or food safety, would be compromised.

Competing with these food science issues, however, is the concern that too much sodium in the diet can lead to increased blood pressure in certain salt-sensitive hypertensive individuals. The NIH recommends that persons consume no more than 2400 mg of sodium per day, yet surveys demonstrate that Americans eat far more sodium than the recommendation (closer to 4000–6000 mg daily). Significant pressure has been placed on food companies to reduce the amount of sodium in processed foods, which, in 1994, resulted in the FDA and USDA defining “healthy” individual foods at 360 mg sodium. The Agencies allowed food companies a 2-year grace period in which to reduce sodium levels to 480 mg, then another 2 years to further decrease these levels to 360 mg.

In 1996, ConAgra Foods filed petitions with the FDA/USDA requesting these agencies to suspend implementation of the 360 mg “rule” for “healthy” stating several reasons, the most significant of which is that a number of processed meats could not, and still cannot be made, at such low sodium levels. Hot dogs will not maintain their integrity at 360 mg, and Honey Ham products, amazingly enough, lose their honey flavor if the sodium is reduced below ~440 mg.

Both agencies granted a “stay” of the lower tier sodium level, and, in fact, have granted several stays because food scientists have not yet identified a suitable sodium substitute. As discussed at length below, several methods have been evaluated, not only by ConAgra Foods, but also by many flavor houses all across the world, in an attempt to reduce sodium levels in processed foods. However, ConAgra Foods’ Healthy Choice meat products still have the lowest sodium levels of any nationally sold processed meat products on the market. In seven of the eight food categories in which Healthy Choice products exist, we are the only food company making a “healthy” product claim.

ConAgra Foods has reduced the sodium in meat products as much as possible, while still manufacturing acceptable products. If every meat (and soup) company reduced sodium as much as Healthy Choice products, there would not be issues associated with sodium consumption. Furthermore, the Healthy Choice line of products (including processed meats) provides consumers with the best brand option for achieving a wide variety of nutritional goals based on the new dietary guidelines.

Regarding food safety, the inclusion of lactate and diacetate has recently become critical in allowing meat processors to manufacture products that can better achieve lower-risk categories [*Listeria* Interim Final Rule (June 6, 2003); Directive 10,240.4 “Microbial Sampling of Ready-to-Eat (RTE) Products for the FSIS Verification Testing Program”(October 2, 2003)]. Thus, the continued availability and use of such antimicrobial compounds remains an important avenue for achieving industry food safety objectives as they relate to *Listeria monocytogenes* (*Lm*) control.

Functional Ingredients in Processed Meats

While there can be many ingredients contributing to the flavor and texture of processed meats, a few are critical to developing the product's characteristic organoleptic properties. These additives also help ensure stability of product quality and safety during shipment, storage and consumption. The industry is continually looking at improved methods to provide consumers with safe products while enhancing quality and making the ingredients statement as simple as possible.

Why sodium?

As Table 1 indicates, sodium is a vital component of many ingredients needed to manufacture high-quality processed meats. The sodium ion itself may or may not have a direct effect on the organoleptic quality and microbial stability of the product; however, it is the most consumer-friendly ion available to link with the "active" anions (Table 1). It has a pleasant flavor with no aftertaste, and it creates a resulting stable molecule.

Table 1
Sodium Containing Compounds in Processed Meats

Sodium chloride – Important for imparting characteristic flavor and texture to processed meats and other foods; key preservative for shelf-life maintenance and food safety.
Sodium nitrite - Color fixation in cured products; protective against <i>Clostridium botulinum</i> spore germination.
Sodium erythorbate - Universally applied as a cure process accelerator.
Sodium lactate/diacetate blends - Currently, the most important application is for <i>Lm</i> suppression; lactate has also been shown to control <i>Clostridium botulinum</i> .
Sodium phosphates - Enhanced water-holding capacity and product functionality; some <i>Clostridium botulinum</i> control has been demonstrated.

Why is it so hard to remove sodium from processed meat formulations?

Table 1 above shows the various compounds used to manufacture and stabilize processed meats which consumers enjoy. Reducing the sodium content affects several product characteristics both directly and indirectly.

a) **Texture** - Salt is the single ingredient other than muscle tissue that allows the manufacture of processed meats. During the manufacturing process, salt extracts muscle proteins, which, upon cooking, form the typical texture found in

franks, smoked sausage and hams. Without salt, ham would simply be cooked pork; Franks would be chopped cooked turkey and pork. As a result of this protein structural change, meat emulsifications for products like hot dogs and bologna more effectively integrate the fat, protein, and water of the formulation.

Sodium also enters the formula through *sodium phosphate*. Phosphate is another ingredient that aids in creating the texture of processed meats. While the sodium ion is not the primary driver in this instance, replacing sodium with potassium results in the bitter aftertaste.

b) Taste – *Sodium chloride* (salt) has a direct impact on the flavor of products. The main mechanism for perception of salty taste in humans is the passage of sodium through ion channels in the taste buds. These ion channels are very specific for sodium ions and only sodium and lithium ions can fit into these “salty” receptors and produce a salty taste. Potassium, because it acts as a carrier for other antimicrobial compounds, is a common sodium substitute, but potassium ions do not produce a salty taste response and instead will produce an extremely bitter/metallic flavor.

To achieve low-risk, processed meats per the current food safety regulations, a combination of lactate and diacetate is required. Other manufacturers can use sodium lactate, but Healthy Choice is forced to use potassium lactate because of the sodium restrictions placed on foods labeled “healthy”. (21 CFR 101.65(d)(2) and 9CFR 317.363 and 381.463) The level of potassium in Healthy Choice processed meats is consequently much higher than other non-healthy-labeled, but still “better for you” processed meats. When using the required amount of potassium lactate to place products in the low *Listeria* Risk category per USDA regulations the potassium level is the same or a little higher than the sodium level. If we were required to lower the sodium level further to 360 mg, the potassium level would significantly exceed the sodium level. This high ratio of potassium to sodium presents extreme flavor challenges; at potassium-for-sodium replacement ratios above 30% potassium, products become very bitter and metallic.

To date, no bitter blocker has proven to be effective to the point where consumers are unable to detect a difference and maintain the same level of purchase intent. Table 2 lists the various sodium replacements that ConAgra Foods has explored. Work continues in this area but “breakthroughs” simply have not occurred even after significant dollars were spent.

c) Color – *Sodium nitrite* is used to impart a characteristic (cured) pink color to processed meats. Without it, cured products would be almost gray in color and unappealing to consumers. *Sodium nitrite* also has the important role of controlling *Clostridium botulinum* in a vacuum packaged product (i.e., hot dogs). Again, the sodium ion is not the primary driver in color development, but comes as part of the sodium nitrite compound.

d) Microbial Inhibition – *Sodium lactate* and *sodium diacetate* are typically used in processed meats to control the growth of various microorganisms, including *Lm*. Each formulation requires research to determine the right balance of these ingredients to suppress microbial growth, but minimize any adverse effects on organoleptic properties (refer to discussion under **Taste**).

In regards to Healthy Choice processed meat formulations, potassium lactate is already being added to enhance food safety. Even at the 480 mg sodium level, the flavor of these products has been compromised as compared to their full sodium counterparts.

Table 2
Some Sodium Replacement Compounds Investigated by ConAgra

Compound	Comments
Potassium chloride	This compound, when combined with sodium chloride at a ratio of two parts sodium chloride to one part potassium chloride, provides a balanced salty taste with some reduction in sodium. Potassium chloride used at a higher ratio than 2:1 has an unpleasant and bitter flavor.
Ribotides	These materials have been commercially available since 1961. Ribotides are used to enhance sweet, salty, and meaty flavors. They are most effective when sodium chloride is present in the food system. Without adequate levels of sodium chloride, Ribotides have an un-natural and unpleasant flavor.
Glutamate salts	These compounds are all used to enhance meaty and savory flavors in foods. They are not acceptable with reduced levels of sodium chloride, nor are they substitutes for sodium chloride.
Yeast extracts	Yeast extracts are other materials that are used to enhance meaty and savory flavors in foods. Some of the components of yeast extracts are similar to Ribotides and Glutamate salts. Yeast extracts do not replace salt, but enhance meaty flavors.
Hydrolyzed proteins	These materials are produced by chemically breaking proteins down into peptides or amino acids. They are very flavorful and meaty tasting, but they are not a substitute for sodium chloride. Hydrolyzed proteins often contain high levels of sodium chloride – up to 40% as a by-product of the manufacturing process.
Bitter blocking/masking agents	We have evaluated a multitude of claimed bitter blocking ingredients. Application is a very a complex issue in that these additives change the characteristic flavor of food.

Listeria monocytogenes (Lm) Control Technologies Investigated

ConAgra has evaluated a number of compounds and technologies in attempting to determine which are most effective in controlling microbial pathogens, particularly *Lm*. In addition to understanding an intervention's potential for achieving microbial lethality and/or suppression goals for RTE meat and poultry products, many studies have been expanded to determine the quality and organoleptic impacts on treated products.

Table 3 summarizes ConAgra Foods' experiences with a variety of antimicrobial interventions. The studies were conducted primarily to determine the effectiveness of these interventions in controlling *Lm*.

Table 3

Various Interventions Investigated to Control Listeria monocytogenes in Processed Meats

Intervention Tested	Antimicrobial Results	Limitations/Issues
Lactate/diacetate (LD) blends	Has shown significant effectiveness in suppressing <i>Lm</i> in cured, processed meats. Sodium salt has become a mainstay ingredient (for most of the industry) in achieving FSIS Alternative 2 status for cured products.	Flavor issues can exist for certain products. Achieving right balance between food safety goals and consumer acceptance has been challenging. Nevertheless, the use of LD is currently the most cost-effective option for <i>Lm</i> control in cured products.
Antifungals (e.g., potassium sorbate)	Sorbate has shown similar effectiveness to LD in controlling <i>Lm</i> .	Sorbate (and other antifungals) is not currently approved as direct additives for processed meats.
Natural antimicrobials (e.g., MicroGard™)	Although in vitro (bench top) studies indicated promising results for <i>Lm</i> control, ConAgra was not able to repeat in actual product applications.	No significant lethality or growth suppression effects observed for <i>Lm</i> .
Acidified calcium sulfate	Has shown significant lethality effects to date. Further investigating potential for <i>Lm</i> suppression in shelf-life studies. If lethality and suppression goals are met, this will allow ConAgra to categorize uncured, turkey breast (not-sliced) items as Alternative 1.	Still need solution for uncured, sliced items.
Glucono-δ-lactone (GDL)	GDL has shown similar effectiveness to LD in controlling <i>Lm</i> .	Organoleptic evaluations were unfavorable for lowest inhibitory levels.
Ozone	ConAgra studies showed this application to be ineffective.	No significant lethality or growth suppression effects observed for <i>Lm</i> .
Ultraviolet light	ConAgra studies showed this application to be ineffective.	No significant lethality or growth suppression effects observed for <i>Lm</i> .
High pressure processing	Well-understood lethal process for controlling vegetative pathogens.	Cost and volume throughput are significant issues.
Low-dose irradiation	Well-understood lethal process for controlling vegetative pathogens.	Currently not approved for RTE meat and poultry applications. In-house testing indicated undesirable sensory results. Cost and throughput could still be hurdles even after approval.
Post-package pasteurization	Lethality goals can be achieved by thermal pasteurization of product surfaces to a specified depth (e.g., 1.5 mm).	Higher costs (capital expenditure) of implementation and having available square footage (footprint) in existing plants remain a challenge. Product purge is a significant quality defect. Consumer/customer acceptance screening with this technology has been limited.

Current Healthy Choice Product Formulations Meet New Dietary Guidelines Committee Recommendations

Healthy Choice brand products fulfill the major recommendations made by the Dietary Guidelines Advisory Committee for the Dietary Guidelines for Americans for 2005. In addition to our processed meat products, the entire product line helps consumers achieve a sensible, healthful dietary balance and variety. The dietary guidelines advisory committee's findings translated into nine major messages for consumers, which are outlined in part E of their report titled Translating the Science into Dietary Guidance. Additionally, part D: Science Base, Section 10 titled the Major Conclusions, draws scientific conclusions from which the recommendations were developed. ConAgra Foods' Healthy Choice product line, which was designed and marketed in 1988 as a "healthy" alternative, fulfills the outlined conclusions and nine major messages by the Dietary Guidelines Advisory Committee.

Nine Messages and Major Conclusions:

- 1) Consume a variety of foods within and among the basic food groups while staying within energy needs. One "Major Conclusion" suggests food patterns should be flexible.
 - Healthy Choice provides healthier versions of traditional foods to fit into a regular diet. The product line is formulated to meet the regulatory criteria for low fat and low saturated fat and is cholesterol and sodium controlled.
 - Healthy Choice delivers a variety of products that fit into all food groups such as bread, lunchmeats, low fat dairy product (ice cream) and frozen meals and soups, which contain a variety of vegetables. All are offered in a variety of convenient packaging.
 - Healthy Choice frozen meals provide less than 400 calories per meal to fit into a 2,000-calorie meal plan. Additionally, other Healthy Choice products offer calorie controlled serving sizes.

- 2) Control caloric intake to manage body weight. Along the same lines, a "Major Conclusion" suggests that consumers need to control portion sizes.
 - Healthy Choice frozen meals provide less than 400-calories per meal and are packaged in single-serve containers.
 - Since all Healthy Choice foods are low fat, they provide fewer calories than the traditional food option.
 - Healthy Choice provides several healthier and nutrient dense versions of many traditional foods which make-up a 2000-calorie diet plan.
 - All Healthy Choice products are required to have at least one nutrient (protein, fiber, vitamin A, vitamin C, calcium or iron) at a good source level or higher—main dish products are required to have two and meals are required to have three.

- 3) Be physically active each day.
 - All Healthy Choice packages illustrate a running man, which promotes a physically active lifestyle.
 - Healthy Choice consumer material always includes the importance of exercise in healthy living.
 - Healthy Choice sponsors such organizations as the American Heart Association and the American Dietetic Association in their efforts to encourage more exercise.

- 4) Increase daily intake of fruits and vegetables, whole grain, and non-fat or low fat milk and milk products.
 - Healthy Choice meals and soups contain a variety of fruits and vegetables in a flavorful way.
 - Healthy Choice products are made with a variety of whole grain ingredients.
 - Healthy Choice ice cream is made with low fat milk and provides calcium.
 - Virtually all Healthy Choice frozen meals provide 10% or more of the DV for fiber.
 - All Healthy Choice products are required to have at least one nutrient (protein, fiber, vitamin A, vitamin C, calcium or iron) at a good source level or higher—main dish products are required to have two and meals are required to have three.

- 5) Choose fats wisely for good health. This is detailed in a “Major Conclusion” that states to decrease consumption of saturated fat, trans fat and cholesterol and increase consumption of unsaturated fat.
 - Healthy Choice foods, by definition are low in saturated fat and cholesterol controlled products. They have virtually zero grams of trans fat and most Healthy Choice products contribute more unsaturated fatty acid than saturated fatty acid.

- 6) Choose carbohydrates wisely for good health. A “Major Conclusion” lists fiber as a nutrient with an intake level low enough to be of concern. An additional “Major Conclusion” is drawn about added sugar in that those who consume large amounts tend to consume more calories but smaller amounts of micronutrients.
 - Healthy Choice frozen meals and soups contain servings of vegetables which provide good carbohydrates like fiber and many of the meat and poultry products do not have significant sugar content, the brand also offers no-added sugar ice cream. Further, Healthy Choice products are made with a variety of whole grain ingredients.
 - Healthy Choice bread is made with whole grain. Healthy Choice product line offers a variety of fibers.

7) Choose and prepare foods with little salt.

- Healthy Choice frozen meals are the only frozen meals that contain less than 600 mg of sodium without compromising taste. Many of these products also contribute potassium through the vegetables as well as the processing ingredients.
- Other Healthy Choice food products also contain controlled sodium (less than 480 mg). In fact, Healthy Choice has the lowest sodium levels of nationally distributed brands in most of the product categories in which it has offerings.

8) If you drink alcoholic beverages, do so in moderation.

- Healthy Choice products do not contain alcohol.

9) Keep food safe to eat.

- All ConAgra Foods products are prepared under HACCP-managed programs with FDA or USDA oversight, thus minimizing food safety risks to consumers. The Healthy Choice line of Ready-To-Eat meat and poultry products are formulated with antimicrobial ingredients to further ensure public health.

Conclusion

Sodium containing compounds continue to play a critical role in allowing food manufacturers to formulate safe, healthy, and organoleptically acceptable processed meat and poultry products. To date, ConAgra Foods has evaluated countless bitter blockers and salt substitutes in an effort to meet the second-tier sodium levels for "healthy" labeled products, which is slated to become law at USDA by January 1, 2006. Additionally, we have investigated a number of food safety interventions, attempting to determine the proper balance between consumer acceptable products and pathogen control.

To date, we have been unable to meet the second-tier targets for "healthy" regulations while achieving both pathogen control and consumer acceptability. Should the government decide to reduce the current "healthy" sodium requirement to the second-tier level, a large majority of Healthy Choice products may well need to be removed from commerce. Once Healthy Choice has disappeared from the marketplace, consumers will be left with only higher fat, higher saturated fat and higher sodium products from which to choose, creating an even greater challenge for them to meet the Dietary Guidelines Advisory Committee's findings as translated into the nine major messages for consumers.