Citizen Petition to the U.S. Food and Drug Administration

by Yoon Ja Kim

According to the guidelines in 21 CFR 10.30, the following Citizen's Petition for the ban of carcinogenic potassium bromate used in the breadmaking process is submitted to the U.S. Food and Drug Administration ("FDA") by Yoon Ja Kim ("Kim"). Kim's website, www.rrkim.com, provides the research results on the benefits of using Slo-C Dough Improver which is a safe, natural, and functional replacement for potassium bromate used in bread production.

A. ACTION REQUESTED

Referring to the FDA's Nov. 29, 1994 letter to Mr. Peter Ranum and copies to professional associations, animal bioassays in the 1980s showed that potassium bromate induced cancer in rats. That is, "we encourage the baking industry to seek safe and suitable alternatives to bromates and to stop using potassium bromate in breadmaking" (1).

Kim has been trying since 1995 to ban carcinogenic potassium bromate used in breadmaking, but industry groups oppose to the ban of potassium bromate and propose to "work toward a voluntary guidance program" on May 14, 1998 (2). Nationwide, California has already taken action for the use of potassium bromate in bakery products, e.g., Proposition 65 requirements (3). An industry-funded study at the American Institute of Baking ("AIB") and jointly with the American Bakers Association reports "possible replacements for PB", i.e., the use of ascorbic acid in combination with azodicarbonamide (ADA), enzymes and/or emulsifiers ("Replacement of Potassium Bromate in White and Variety Breads", AIB Tech. Bull. Vol. XIII, July 1991).

Kim viewed the industry's problem using a fresh approach and came up with a novel solution to replace potassium bromate in breadmaking. Petitioner requests that the Commissioner support a slow acting ascorbic acid ("Slo-C") Dough Improver as a functional replacement for bromates used in bread production. The basis for this request is Slo-C Dough Improver as an effective dough improver for its intended use, bringing about improvement in the baking qualities of the flour by modifying the structure of proteins during dough production of yeast-leavened products.

B. STATEMENT OF GROUNDS

Until its ban in the United Kingdom ("U.K.") in 1989, potassium bromate is added by the flour mill or baker as a dough conditioner in bread manufacture. The highly reactive potassium bromate breaks down to the inactive bromide during dough fermentation and baking. This breakdown was always considered to be complete; now, sensitive analytical techniques detect some bromate residues in the bakery products. The concerns about the toxicity of potassium bromate have necessitated that the food industry reexamine the use of potassium bromate in breadmaking.

1. The FDA Standards of Identity for Bakery Products and Flour

Under the provisions of 21 CFR Parts 136 (Bakery Products) and 137 (Flour), the FDA limits the level of all oxidizing agents permitted for use in breadmaking, except ascorbic acid. Those levels are based on the amounts of flour used in the baked products – that is, bromates and iodates should not exceed 75 parts per million (singly or in combination) of flour used in the bread formula. In

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particular, the FDA Standards in the U.S. permitted the addition of ascorbic acid only to flour at levels not to exceed 200 ppm, but not bread. Thus, a petition in January 1970 to permit the use of ascorbic acid by baker was submitted and become effective on September 15, 1970.

2. Potassium Bromate as an Oxidizing Improver

The Committee on the Toxicity of Chemicals in Food, Consumer Products and the Environment in the U.K. requested that further studies be carried out on bromate levels in bread. In 1988, a survey conducted in the U.K. documented bromate levels in the range of 20-300 parts per billion (ppb) in commercial samples of breads assayed (4). A survey conducted by the U.S. FDA reports bromate levels of 30 ppb to 1 part per million (ppm) in bakery products marketed in the U.S. (1). The detectable levels of potassium bromate were considered to be undesirable, resulting in a ban of the use of potassium bromate in bakery products in the U.K. in 1990. Canada and Japan later implemented their own bans. For many European countries, ascorbic acid is now the only approved oxidizing agent (i.e., dough improver) used in the breadmaking process.

a) Oxidizing Agents on Gluten Proteins

Bakers have used potassium bromate in breadmaking for over 90 years. A paper, "Bromate – What Does It Do?" presented at 67th American Society of Bakery Engineers meeting in Chicago, Illinois, March 1991 reports at page 181, "it is clear that we do not understand the action of potassium bromate." Then, Dr. Hoseney states that the early research work strongly suggests that "the improving action of potassium bromate is not just an oxidation" and the mechanism of oxidizing agent's action that bromate reacts with thiol groups of proteins is unknown.

Oxidizing agents such as potassium iodate (KIO_3) and potassium bromate ($KBrO_3$) "give up oxygen during reaction with flour" (AIB Tech. Bull. Vol. III, June, 1981), forming end products of KI + 3 oxygen and KBr + 3 oxygen, respectively. Both provide three molecules of oxygen, but have different rates of reaction during dough processing – that is, bakers use KIO_3 as a fast oxidizing agent and $KBrO_3$ as a slow oxidizing agent in breadmaking processes.

In analytical methods of standardization of sodium thiosulfate solution, potassium iodate or potassium bromate is a primary standard for thiosulfate solution and the liberated iodine is titrated in slightly acidic solution. However, the reaction is somewhat slower when potassium bromate is used as the primary standard for thiosulfate solution. These facts clearly indicate that the acids (acetic, lactic, and succinic acids) produced by yeast during fermentation lead to different rates of reaction of potassium iodate and potassium bromate during dough processing.

In fact, the presence of iodide or bromide ions in the dough has its effect in the role of oxidizing agents on protein structure through "Salt Effects on Conformational Stability", bringing about partial unfolding of gluten proteins during dough production of yeast-leavened products. Due to the fact that bromide ion is more slowly generated than iodide ion during dough processing, the iodide ion generated at low pH makes potassium iodate to be functional during the early stages of proofing and then, the bromide ion generated at lower pH levels makes potassium bromate to be functional during the later stages of proofing and early stages of baking.

The oxidation of glutenin subunits (in *Wheat Gluten*, eds. P.R. Shewry and A.S. Tatham, RS.C Cambridge, U.K., 2000; pp. 223-226) was studied using inorganic oxidants (i.e., KIO_3, $KBrO_3$, or

H_2O_2). The study of salt effects on glutenins confirmed, "high concentrations of KIO_3 negatively affected polymerization in 'single step' oxidations." That is, iodide or bromide ions in the dough matrix actually enhance protein unfolding, bringing about the transition of helix, native protein to random coil during dough production of yeast-leavened products.

b) Ascorbic Acid on Gluten Proteins

Ascorbic acid ionizes in two stages in aqueous solution; ascorbate free radical formed from the loss of the first hydrogen ion is a moderately weak acid and dehydroascorbic acid formed from the loss of the second is a very weak acid. The fact that adding ascorbic acid to dough brings about the structural changes in protein induced by pH changes is known as "pH-induced Conformational Changes." This structural change of gluten proteins induced by changes in pH (i.e., at low pH) is correlated with exposure of SH groups that are buried within the structure of the gluten proteins. Therefore "increasing ascorbic acid concentrations up to 100 mg/kg of flour caused an increase in the concentration of free SH groups by approximately 35%"(in *The Gluten Proteins*, eds. D. Lafiandra, S. Masci and R. D'Ovidio, RS.C, Cambridge, U.K., 2004; pp. 357-360).

Due to its unstable nature of dehydroascorbic acid, bread manufacturers use ascorbic acid in their bread production. The oxidation of ascorbic acid to reversible dehydroascorbic acid and further to irreversible diketogulonic acid is enhanced by trace metal ions. The studies done on ascorbic acid strongly support that when bakers add L-ascorbic acid to bread mix as part of Slo-C Dough Improver, ascorbic acid (i.e., ascorbate free radical, dehydroascorbic acid, diketogulonic acid) bring about the structural changes in proteins during dough production of yeast-leavened products. Adding L-ascorbic acid to the dough partially unfolds polypeptides; in fact, partially unfolded disaggregated gluten protein structures decreased G' and slightly increased the slope of the G" curve, "indicating that the gluten structure was weakened by L-AA addition to the dough" (in *Wheat Gluten*, eds. P.R. Shewry and A.S. Tatham, RS.C, U.K., 2000; pp. 239-243).

In summary, potassium bromate or ascorbic acid used in bread production does not act as a dough oxidizing agent or a dough strengthener. Kim's research conducted with "Effects of Food Acids in Breadmaking Processes" leads to the conclusion: 1) potassium bromate or ascorbic acid functions as a dough improver by modifying the structure of proteins during dough production of bread; 2) mainly acetic acid produced by yeast during fermentation has an oxidizing effect (i.e., actually improving effect on dough structure of proteins), reducing the potassium bromate requirement from about 60 ppm in the No Time dough process to about 15 ppm in the Sponge Dough process; and 3) strengthening the dough structure of gluten proteins is actually achieved by inter- and/or intramolecular bonds between positively charged proteins and negatively charged metal ion-food acid complexes in the dough matrix, resulting in a significant increase in bread volume.

3. Development of Slo-C Dough Improver used in Breadmaking

As a new product developed for use in bread manufacture, petitioner submits full reports of investigations that establish Slo-C Dough Improver as a safe and effective dough improver for its intended use. Kim's website, www.rrkim.com, provides Kim's research results, establishing how Slo-C Dough Improver functions as a dough improver and the benefits of using Slo-C Dough Improver in breadmaking for bread manufacturers and consumers who desire healthier bread. Kim's 3/03/2006 letter to Dr. James Wallwork enclosed "Addenda to My Research" that supports experimental facts of the study results of Slo-C Dough Improver posted on Kim's website.

a) Establishment of Controls

For a comparison study of different food acids and controls, Kim used the result of 15 ppm potassium bromate by AIB (5), 75 ppm ascorbic acid, and the bread made from 75 ppm ascorbic acid and 0.08 part citric acid per 100 parts flour. The reasons are: 1) the AIB study revealed that specific loaf volume of 6.01 cc./g. was obtained from a combination of 15 ppm potassium bromate added and the acids produced by yeast during 3.25 hours fermentation time; 2) Kim's study revealed that the acetic acid naturally produced by yeast during sponge fermentation provides non-colloidal metal ion-acetate complexes, while the citric or malic acid added as part of potassium bromate replacer I (one) to bread mix provides colloidal aquo-metal ion-citrate/malate complexes to the dough matrix; and 3) among food acids studied, adding 75 ppm ascorbic acid and 0.08% citric acid to bread mixes produced the best quality bread.

b) Use Levels of Food Acids in Breadmaking

Kim's studies conducted with citric and malic acids on 3/27/1992 were repeated on 12/15/1992 to determine the lower limit (0.015%, 150 ppm) of food acid with citric and malic acids, which have good chelating powers, while the upper limit (0.2%, 2000 ppm) was determined from acetic acid that has weak chelating power. Further, Kim's studies with citric and malic acids on 3/37/1992 and 12/15/1992 were repeated on 6/01/1993 at Highland Baking Co., in Lincolnwood, Illinois to reevaluate "proper amounts" of food acid levels in potassium bromate replacer I (one) and dividing quantity of potassium bromate replacers I and II with dipotassum phosphate, establishing that 0.1% malic acid is "proper amounts" and dividing quantity. Despite 0.2% acetic acid per 100 parts flour is recommended, acetic acid provides non-colloidal metal ion-acetate complexes to the dough matrix, producing coarser crumb grain than citric acid; thus, 0.1% food acid is used as dividing quantity between potassium bromate replacer I (one) and potassium bromate replacer II (two), as written in Example 1 of U.S. Patent No. Re. 36,355 ("'355").

To eliminate the effect of food acids (i.e., acetic, lactic, and succinic acids) naturally produced by yeast during sponge fermentation, the No Time dough process is used to evaluate the effects of different food acids on dough development of gluten proteins during dough production, and crumb grain and texture in finished bread characteristics. The AIB's and Kim's studies established that potassium bromate replacer I (one) given in Example 1 (75 ppm ascorbic acid and 0.08% citric or malic acid) will produce better quality bread than when using 15 ppm potassium bromate and the acids produced during 3.25 hours sponge fermentation time. The combined effects of ascorbic acid and citric acid on the dough structure of proteins resulted in increased loaf volume of bread that has finer crumb grain and longer shelf life than bread produced from potassium bromate.

c) Functional Effects of Food Acids in Breadmaking

Kim's research with different food acids revealed that the acids produced by yeast during fermentation or food acids added to bread mix bring about the structural changes in gluten proteins during dough processing, properly developing the dough structure of proteins in bread production. Table 1 of Dr. Hoseney's baking data also revealed that 50 ppm ascorbic acid combined with 0.015% tartaric acid produced "sl more oxidized than 50 AA" and 50 ppm ascorbic acid combined with 0.025% tartaric acid produced "sl more oxidized than 50 AA + 0.015 tartaric acid", respectively. That is, the acid (i.e., acetic acid) produced by yeast during fermentation or tartaric acid added to bread mix has an oxidizing effect (i.e., actually improving effect on dough structure of proteins) in bread production, e.g., reduction in the potassium bromate requirement from about 60 ppm in the No Time dough process to about 15 ppm in the Sponge Dough process.

Further research on 6/01/1993 revealed that the levels of food acid added to bread mix as part of potassium bromate replacer I (i.e., Slo-C Dough Improver) are crucial because all food acids studied improve the functional properties of flour proteins up to a certain point. When more than 0.1% food acids are added to bread mixes, citric, malic, and tartaric acids bring about substantial structural changes in gluten proteins than acetic acid during dough production. Consequently, the use of proper food acid levels (i.e., "effective amounts" is written as "proper amounts" in Kim's notebook) combined with ascorbic acid produces the properly oxidized dough (i.e., properly developed dough structure) by slowly converting ascorbic acid to dehydroascorbic acid and by providing hydrogen ions and metal ion-food acid complexes to the dough matrix during dough production of yeast-leavened bread. The resulting breads produced with Kim's potassium bromate replacer I (one) have the highest, uniform quality bread from basic ingredients (e.g., flour, water, yeast, salt, sugar) used in breadmaking, without adding dough conditioners such as emulsifiers.

Kim's potassium bromate replacer II (two) includes dipotassium phosphate that enhances dough stability through emulsification. To observe the beneficial effect of dipotassium phosphate on dough properties in bread production, Kim studied series of the baking tests conducted with 0.1% different food acids and 0.25% dipotassium phosphate. Kim's baking test of 6/22/1993 was 0.1% tartaric acid and 0.25% dipotassium phosphate, commenting on bread with slightly overproofed dough and "It appears that slow dissociation of complexes occurred during proofing period"; and those of 6/30/1993 were 0.1% fumaric acid and 0.25% dipotassium phosphate, 7/12/1993 were 0.1% oxalic acid and 0.25% dipotassium phosphate, and 7/26/1993 were 0.1% lactic acid powder (60% lactic acid and 40% calcium lactate) and 0.25% dipotassium phosphate that produced "substandard quality breads in volume and internal characteristics", respectively.

In essence, Kim's research with food acids resulted in complete understanding of fermentation dough development and essential role/function of gliadin proteins in breadmaking quality of wheat flours, especially strength and stability of the dough structure required for the production of quality bread. The experimental facts establish that as fermentation proceeds, a decrease in pH induces the protein unfolding and cross-linking in the dough matrix. Thus, the gluten structure that exists in the fermented dough is the result of an enormous number of inter- and/or intramolecular interactions, primarily noncovalent bonds, which occur between positively charged proteins and negatively charged aquo-metal ion-food acid complexes during dough production. These strong noncovalent bonding contribute to strength and stability of the dough structure, affecting its ability to form thin, extensible films that allow for gas retention during proofing and baking process.

d) Reduction in Sponge Fermentation Time

The use of the patented Slo-C Dough Improver not only replaces potassium bromate, other oxidizing agents, and additives used in bakery products, but also shortens sponge fermentation time. As shown in Example 1, Kim recommended potassium bromate replacer II, when 0.1% food acid is used. Then, when Kim evaluated acetic acid in the Sponge Dough process, Kim further observed that potassium bromate rplacer I (one) is successfully used with 0.1% citric, malic, and tartaric acids and 250 ppm ascorbic acid. Using a shorter sponge fermentation time in the Sponge Dough process, bakers divide the total amounts of 0.1% acids and 250 ppm ascorbic acid into 60% added with sponge ingredients and 40% added with dough ingredients. The resulting breads had better volumes and finer crumb grains with citric and malic acids but coarser crumb grain with tartaric acid than the bread produced with 15 ppm potassium bromate added and the acids produced during 3.25 hours sponge fermentation time. This reduction in the sponge fermentation time results in significant cost reduction in a manufacturing cost of bakery products, while still retaining the desirable dough properties and bread quality.

In fact, the use of Slo-C® Dough Improver in the Sponge Dough process is significantly reduced sponge fermentation time to 2 hours or less, providing fermentation by-products (i.e., acetic acid, lactic acid, and succinic acid) as citric acid in the manufacture of yeast-leavened products. Even if a shorter sponge fermentation time is used, the use of Slo-C® Dough Improver rapidly brings about the desirable dough properties that hold entrapped gases in minute droplet size and prevent droplets from joining into larger drops during baking. The bread characteristics are identical with bread obtained by bulk fermented sponge, namely

1) Citric acid brings about greater structural changes in gluten proteins than acetic acid [one hydrogen ion (H^+) and one acetate ion (acetate$^-$)], providing 3 hydrogen ions (3 H^+) and 3 citrate ions (citrate$^-$, citrate^{--}, citrate^{---}) when ionized (i.e., Ionization Constants of Weak Acids).

2) The acetic acid naturally produced by yeast during fermentation forms non-colloidal metal ion-acetate complexes that act as a fair dough improver and a less effective crumb softener, but do not act as a good emulsifier in the dough matrix, whereas citric acid forms colloidal, aquo-metal ion-citrate complexes that act as an excellent dough improver/emulsifier in the dough matrix and effective crumb softener in bakery products.

3) Slow conversion of ascorbic acid to dehydroascorbic acid in the dough causes part of ascorbic acid in Slo-C® Dough Improver to react as a reducing agent, contributing to a softening effect on dough properties that normally take place during bulk fermentation.

In summary, "old sponge" (i.e., acetic acid in lengthy fermentation) is known to produce bread with "an open, uneven, and streaky grain." The obvious way to remove acetic acid in the sponge dough is to shorten a sponge fermentation time. Then, Slo-C Dough Improver added at the sponge stage provides citric acid to the sponge dough. In consequence, the advantage of Slo-C Dough Improver in the Sponge Dough process shortens the fermentation requirement – that is, using a shorter fermentation time, the recommended usage for Slo-C Dough Improver is increased by adding about 60% at the sponge stage and about 40% at the dough stage.

4. Slo-C Dough Improver as a Replacement for Potassium Bromate in Breadmaking

The pH dependency of metal ion-food acid complexes in bread production (col. 5, ll. 7-34 of the '355 patent) makes food acid to be "effective acid" for use in Kim's slow acting ascorbic acid composition [Nanda et al. J. Indian Chem. Soc. 35, 355 (1958)]. The study results conducted with different food acids leads to the development of Kim's potassium bromate replacer composition consisting essentially of about 0.001 to 0.03 part ascorbic acid, about 0.015 to 0.2 part food acid having chelate-forming properties, and flour in the manufacture of yeast-leavened products (claim 5). The use of ascorbic acid combined with "effective amounts" of effective food acid not only "slows down oxidation of ascorbic acid to dehydroascorbic acid during a manufacturing process of yeast-leavened products" (claim 6), but also provides hydrogen ions and negatively charged metal ion-food acid complexes to the dough matrix in bread production. Inter- and/or intramolecular bonding between positively charged flour proteins and negatively charged metal ion-food acid complexes in the dough matrix actually strengthens and stabilizes the dough structure of flour proteins during dough production. That is, functioning as an excellent dough improver/emulsifier and effective crumb softener, the use of ascorbic acid and citric acid added to bread mix produces better quality bread than bread produced from the use of potassium bromate in breadmaking.

In particular, the experimental facts also establish that the use of ascorbic acid combined with effective amounts of effective food acid produces the properly oxidized dough (i.e., actually properly developed dough structure of proteins) that is strengthened and stabilized by inter- and/or intramolecular bonds during mixing, proofing and baking. Thus, "the potassium bromate replacer provided in the present invention is a more effective oxidant than potassium bromate because potassium bromate has little effect on oxidation of dough during mixing and the early stages of proofing" (col. 3, ll. 1-5 of the '355 patent). Thus, Kim requests the FDA to support Slo-C Dough Improver as a safe, natural, functional replacement for potassium bromate in breadmaking.

a) Functional Effects of Potassium Bromate Replacer on Bread Quality

The functional effects of Kim's potassium bromate replacer improve the baking qualities of the flour, bringing about the modifications in dough structure of gluten proteins to improve its ability to retain gas during proofing and baking process. That is, the principal effect of Slo-C Dough Improver's action during dough production modifies the structure of flour proteins, producing well developed dough matrix with thin, extensible films required for the production of bread products.

In particular, the improvement in bread quality (e.g., specific loaf volume, crumb grain, shelf life) depends primarily on which food acid combined with ascorbic acid is used during dough processing of yeast-leavened products. As examples, Slo-C Dough Improver has been successfully tested in the production line of commercial bakery on July 10, 1996. Hamburger Buns made from potassium bromate replacer I (e.g., Example 1 of the '355 patent) at Coldwater Bakery in Michigan had comparable loaf volume and improved (i.e., finer) crumb grain than the control (i.e., regular production batch). Kim also found that 75 ppm ascorbic acid and 0.08% tartaric acid added as part of bromate replacer I (one) produced the bread with increased loaf volume, as comparable to 75 ppm ascorbic acid and 0.08% citric acid but produced coarser crumb grain than citric acid. Non-colloidal metal ion-tartrate or mteal ion-acetate complexes in the dough matrix produce coarse crumb grain, as compared to colloidal metal ion-citrate/malate complexes.

b) Strengthening Dough Structure of Proteins during Dough Production

The dough mixing process brings ascorbic acid and food acid together as a prerequisite for their reactions. The formation of gluten structure achieved during mixing is further developed by yeast fermentation – that is, yeast will grow and develop the flour proteins of dough producing carbon dioxide gas and the acids during sponge fermentation, contributing to increasing strength and stability of the dough structure in bread production. Specifically, the fermentation of dough involves complex interaction of flour proteins with other constituents of dough. Many types of bonding such as covalent, hydrogen, ionic, and apolar bonds contribute to proper extensibility and gas retention of the fermented dough. Thus far experimental facts strongly supporting the role of flour proteins in determining breadmaking quality provide evidence that positively charged groups of proteins (albumins, globulins, gliadins, glutenins) and negatively charged metal ion-food acid complexes directly influence strength and stability of the dough structure through noncovalent bonding such as protein-protein interaction, protein-(metal ion-food acid complex) interaction, or protein-(metal ion-food acid complex)-protein interaction.

As a result, Kim explains that "the properly oxidized dough is produced throughout the entire manufacturing process of yeast-leavened products" means "the properly developed dough structure that is strengthened and stabilized by noncovalent bonding throughout the entire manufacturing process of yeast-leavened products." The combined effects of ascorbic acid and food acid used in breadmaking change a fast ascorbic acid oxidant to act as a slow acting oxidant that is functional throughout the entire manufacturing process of yeast-leavened products (claim 7); and said ascorbic acid is a more effective oxidant (i.e., dough improver) than ascorbic acid when used alone during a manufacturing process for making yeast-leavened products (claim 8).

5. Function of Gluten Proteins in Bread Production

To increase loaf volume of bread, vital gluten is added to Multi/Whole grain/high fiber bread mixes; however, cereal chemists do not know how gluten proteins achieve the strengthening of dough structure in bread production. Kim's study on effect of different food acids in breadmaking established that to produce desirable dough properties and high quality bread, it is essential to modify the dough structure of proteins by the acids produced during yeast fermentation or by Kim's potassium bromate replacer in bread production. That is, the modifications in dough structure of flour proteins must occur to improve its ability to retain gas during proofing and baking process, contributing to the ability of gluten proteins to form thin extensible films required for the production of quality bread products. Currently, bread manufacturers utilize Kim's research results for the functional effect of acetic acid on the dough structure of proteins during dough production – that is, vinegar (i.e., a solution of acetic acid) included in dough ingredients develops the remaining flour (30-40% at dough stage) added to the fermented sponge dough.

There is no direct correlation between structure of gluten proteins and functionality of flour quality. This is due to the fact that inter- and/or intramolecular interactions of positively charged gliadins with functional groups of proteins (i.e., albumins, globulins, glutenins) and other constituents (e.g., metal ion-citrate, malate, tartrate, and/or acetate complexes, etc.) of dough play a crucial role in determining the dough structure of proteins in the fermented dough. Kim's study results lead to the conclusion that primarily noncovalent bonds affect its ability to form thin, extensible films that allow for gas retention during proofing and baking process, resulting in considerable improvement in bread volume, crumb texture and grain of loaves.

6. Labeling of Slo-C Dough Improver

Ingredients such as bromates, iodates, ADA, ascorbic acid have been labeled on packaging of bread and rolls as "dough conditioner" under the authority of TR 94 issued by the FDA. Then, new labeling regulations issued by the FDA become effective in January 1, 1978, requiring full labeling by complete chemical name. When Slo-C Dough Improver is added to bread mixes, ascorbic acid and food acid are labeled as dough improvers that improve the baking qualities of the flour by modifying the structure of proteins during dough production of yeast-leavened bread.

All products introduced into interstate commerce require the disclosure of all ingredients used in the manufacture of bakery products, except those that qualify as incidental. Kim's Slo-C Dough Improver are diluted with yeast food or vitamin/mineral mix for convenience in measuring them in commercial bakeries that use starch as fillers, instead of flour. In particular, citric acid is a natural product produced by fermentation. Thus, all bakery products made with Slo-C® Dough Improver containing ascorbic acid and citric acid are labeled as "natural" products.

7. Recommended usage for Slo-C Dough Improver

Slo-C® Dough Improver is added both in sponge and dough ingredients to produce the properly developed dough structure of gluten proteins and better volume expansion during baking process. Recommended usage for Slo-C® Dough Improver I and II is 2-12 ounces (0.125-0.75%) per 100 pounds of flour. Optimum usage will vary depending on degrees of water hardness, strength of flour used, the type of bread desired, and methods of breadmaking processes. Bakers can add an additional ½ to1 ounce of Slo-C® Dough Improver to alkaline water and add less than ½ to 1 ounce Slo-C® Dough Improver to acidic water, compared to normal requirement of Slo-C® Dough Improver for neutral or slightly acidic water.

The functional effects of Kim's Slo-C Dough Improver improve the baking qualities of the flour, bringing about the modifications in dough structure of proteins in some other way than by lengthy fermentation step. Thus, the use of Slo-C Dough Improver shortens a sponge fermentation time. Using a shorter fermentation time, the recommended usage for Slo-C Dough Improver is increased by adding about 60% at the sponge stage and about 40% at the dough stage. Adding an additional ½ to 1 pound of water to each pound of Slo-C® Dough Improver is also suggested due to increased water absorption provided by aquo-complexes of metal ion-food acid in the dough matrix.

C. ENVIRONMEMTAL IMPACT

Kim believes that the actions requested herein qualify for a categorical exclusion from the requirement of issuance of an environmental assessment under 21 CFR 25.40 (a)(2005). In any case, Kim believes that there will be positive environmental impact requested in this petition. This is due to the fact that as we understand the mechanism of oxidizing agents' action and fermentation dough development during dough production of bread, chemical oxidizing agents (i.e., bromate/iodate, or ADA) are not required to produce quality bread.

D. ECONOMICAL IMPACT

To produce bread with "no time" doughs in the mid-1950s has its obvious advantages, but such doughs were never popular because of the inferior quality of the bread they produced. Thus, from the turn of the century until the present time, the Sponge Dough process that requires four-hour sponge fermentation time produced the majority of bread and rolls. The justification for lengthy sponge fermentation is the fermentation products (i.e., acids) produced by yeast in the fermented dough, bringing about the modifications of dough structure to improve its ability to retain gas during proofing and baking process. In fact, bakers achieve proper modifications of optimum gluten structure by Kim's Slo-C Dough Improver added as part of bread mix, rather than by lengthy sponge fermentation step. As a result, Kim's Slo-C Dough Improver enables bakers to successfully use a shorter sponge fermentation time in the Sponge Dough process, significantly reducing overall production costs of bakery products.

Kim's new, effective Slo-C Dough Improver will increase the company's growth and profitability. This is due the fact that the use of Slo-C Dough Improver in breadmaking brings about greater modifications in dough structure by the combined effects of ascorbic acid and citric acid than the acetic acid produced by yeast during lengthy sponge fermentation. As a functional replacement for potassium bromate in breadmaking, the economical benefits provided by the use of the patented Slo-C® Dough Improver (e.g., ascorbic acid and citric acid) in bread production are:

1) Significant cost reduction by shortening sponge fermentation time from 4 hours to 2 hours or less, while still retaining the desirable dough properties and bread quality.

2) Bread product quality that cannot be achieved with any other products currently available – that is, the combined effects of ascorbic acid and citric acid on gluten proteins produce the properly developed dough structure that is strengthened and stabilized by noncovalent bonds, improving the quality of bread with greater loaf volume, finer crumb grain, and longer shelf life.

3) Reduction in the amount of soybean oil from 2.5 to 3% to about 0.5 to 1.0% and also complete elimination of emulsifiers such as SSL, EMG, or DATEM, due to the presence of colloidal metal ion-citrate complexes in the dough matrix.

4) Development of new, unique bread products, e.g., for consumers who prefer softer white bread and controlled carbohydrate bread, it is recommended all natural high-protein bread that delivers health benefits of whole grain breads without sacrificing taste and texture of white bread that increases the total protein content to about 33%, balances essential amino acid (Lysine) that is deficient in wheat flour, and provides fiber content of whole grain bread.

Scientific evidence in this petition has demonstrated that the use of Slo-C Dough Improver (e.g., ascorbic acid and citric acid) in breadmaking not only produces natural bread that has greater loaf volume, finer crumb grain and texture, and longer shelf life than bread produced from potassium bromate, but also achieves about a *one-third reduction* in manufacturers' current cost of yeast-leavened products. In addition, based on the facts established in Gluten Structure-Functionality Relationships, breeders/genetic engineers can approach the development of new wheat varieties.

E. CERTIFICATIONS

The undersigned certifies that to the best of Kim's knowledge and belief, this petition includes all information on which the petition relies, and that it includes representative data known to Yoon Ja Kim which is supportive to the petition.

Dare: April 24, 2006

Respectfully submitted,

Dr. James C. Wallwork
Division of Petition Review (HFS-265)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

Yoon Ja Kim
Yoon Ja Kim
913 Frances Parkway
Park Ridge, Illinois 60068
Tel. (847) 823-2444