



March 5, 2007

Docket Clerk  
United States Department of Agriculture  
Food Safety and Inspection Service  
300 12<sup>th</sup> Street S.W., Room 102 Cotton Annex  
Washington DC, 20250

**Re: Comment to FSIS Notice of Hormel Petition and Public Meeting on the Definition of the Term "Natural" (Docket No. FSIS 2006-0040E)**

Dear Sir or Madam:

Farmland Foods, Inc. ("Farmland") respectfully submits this comment in response to the Food Safety and Inspection Service's ("FSIS" or "agency") notice of petition and request for comments on "Product Labeling: Definition of the Term 'Natural,'" published in the *Federal Register* of December 5, 2006,<sup>1</sup> and Hormel Foods Corporation's ("Petitioner") October 9, 2006 petition ("Petition") requesting a change in the United States Department of Agriculture's ("USDA") agency policy.<sup>2</sup>

Farmland is one of the nation's largest food manufacturers. Now a part of the Smithfield Foods family, the Farmland business began in 1959 as part of a farmer-owned cooperative. Farmland maintains a proud heritage of producing quality meat products for today's demanding consumers. As a livestock purchaser, food processor and seller in domestic and international markets, the company is honored to be a part of our nation's agricultural system.

For many years, Farmland has maintained a productive working relationship with the USDA and FSIS and is currently an active participant in the rapidly growing market for natural products. We are deeply concerned, however, with recent agency activity that threatens to reverse longstanding agency policy and alter the regulatory landscape in a way that harms both consumers and businesses.

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<sup>1</sup> 71 Fed. Reg. 70503 (December 5, 2006); 72 Fed. Reg. 2257 (January 18, 2007).

<sup>2</sup> Hormel Foods Corporation, *Petition for the Issuance of a Rule Regarding Natural Label Claims*, (October 9, 2006), found at [http://www.fsis.usda.gov/Regulations\\_&Policies/Petition\\_Natural\\_Label\\_Claims/index.asp](http://www.fsis.usda.gov/Regulations_&Policies/Petition_Natural_Label_Claims/index.asp).

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This activity, both in the substance of its reasoning and in the procedures it has employed, merits careful review. Because this is a matter of some urgency, we respectfully request that the agency promptly and carefully consider the following:

- We request that the agency maintain its policy of allowing potassium lactate, a natural substance derived from corn, to be used as an ingredient in meat products sold under the “natural” label, and
- We request that the agency refrain from taking steps that would change policy without fair and open discussion among those affected by the proposed changes.

Granting these requests would preserve the agency’s long-standing practice of responsible, flexible rulemaking and further its mission of promoting food safety and safeguarding the public trust.

## **I. Summary**

This matter involves unilateral changes to longstanding agency policy on the labeling of natural products. The changes contemplated, if allowed to proceed, would provide a significant economic advantage to one competitor in the natural products market. They would deny many others a legitimate and accepted method of production. These changes are not in the public interest, nor in the interests of the manufacturers and producers of natural products and ingredients.

For centuries, food producers have used a variety of natural processes to enhance meat quality, making it more flavorful and safe for consumption. One of these methods is the use of salt, a natural ingredient valued for its flavoring effect and its preservative qualities. Lactate is a common salt derived from lactic acid, a natural product. Because lactates are natural substances, they have long been considered natural ingredients. FSIS’ longstanding policy has recognized this and has allowed the use of lactates in products bearing the “natural” label. The dual quality of lactates - the flavoring and preservative functions - have been recognized for years. The agency has consistently taken both functions into account as it has developed regulatory policy and practice.

The policy for the use of the word “natural” in labeling has developed through the normal course of agency decision-making. It has served the markets well in providing consumers a variety of choices in natural products. Farmland and many other food manufacturers have relied upon this natural policy. Farmland, for example, uses potassium lactate at the flavoring levels established by the agency. Many companies, Farmland included, have created product lines and adopted manufacturing processes based on the policy. They have also made significant commitments to suppliers and customers. Many have product in inventory carrying or intended to carry labels approved under the policy. Recent proposed policy changes and the threatened action of rescinding current label authorizations would therefore have a severe adverse economic impact on these companies - costs can easily exceed \$1 million for one product line alone. Moreover, withdrawing

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or rescinding current labeling authorizations would foreclose the ability of these competitors to develop current and future product lines in the emerging natural market. This would deny manufacturers using natural ingredients a crucial opportunity to serve their market. It would cause irreparable harm to existing and prospective customer relationships.

Petitioner uses a different technology to produce natural products: a sophisticated, high-pressure processing system that utilizes multi-million dollar equipment to apply 87,000 pounds of pressure per square inch to Petitioner's products. This high-pressure process does not use the traditional technique of adding natural ingredients to achieve enhanced flavor and longer shelf life. In a word, the Petition appears to be an attempt to restrict the ability of Hormel's competitors to produce and market natural products.

The FSIS, apparently yielding to Petitioner's argument, has unilaterally changed its longstanding policy and taken steps to disallow the use of lactate in products labeled "natural." The FSIS has sent letters to various companies, including Farmland, that have existing label approvals for natural products containing lactate. These letters threatened to revoke the approvals unless the companies established that the lactate used has no microbial effect on the finished product or any impact on shelf life or use-by dating.

These actions by FSIS could provide Petitioner with a significant economic advantage in the market for all natural products and are not justified under FSIS' longstanding natural policy. Under FSIS and Food and Drug Administration ("FDA") regulations, lactate is a natural flavor that FSIS recognized as also having a preservative function but is not a "chemical preservative" prohibited by the FSIS natural policy. In addition, there is no evidence whatsoever that consumers are misled by a natural label on a product containing lactate.

Farmland understands that the FSIS may need to examine current regulations and seek to establish additional guidelines regarding use of the word "natural." It is clear that as food processing technologies develop, new considerations come into play. Advances in food production, processing, and ingredients will always raise new issues related to selecting which food products should be eligible for the "natural" label. Changes in the current regulatory framework, however, should be made with deliberation, and with notice and comment rulemaking. Farmland strongly opposes *ad hoc* efforts to make changes in labeling policy.

Farmland believes that the recent change to the August 2005 natural policy is ill advised. Moreover, when coupled with the demand letters, FSIS policy changes have effectively established a new mandatory standard. These actions are arbitrary and capricious, and constitute rulemaking subject to the notice and comment requirements of the Administrative Procedures Act ("APA"). In addition, this change may well be a "significant guidance document," requiring the approval of the Office of Information and Regulatory Affairs ("OIRA") in the Office of Management and Budget ("OMB") and the opportunity for public comment under Executive Order 12866. Finally, Farmland believes

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that FSIS' restrictions on truthful and non-misleading natural claims unfairly restrict commercial free speech.

## II. Background

### A. FSIS Natural Policy

FSIS approves labels for meat and poultry products under its jurisdiction.<sup>3</sup> As part of this regulatory regime, FSIS publishes the "Food Standards and Labeling Policy Book" ("Policy Book"), which serves as guidance to help manufacturers prepare product labels that are truthful and non-misleading.<sup>4</sup> Among other things, this Policy Book contains guidance on when the term "natural" can be appropriately used on the labels of meat and poultry products.

The original natural policy, which was issued over 23 years ago on November 22, 1982, stated that the term "natural" may be used on labeling for meat and poultry products provided that: (1) the product does not contain any artificial flavor or flavoring, coloring ingredient, or chemical preservative (as defined in 21 CFR § 101.22), or any other artificial or synthetic ingredient; and (2) the product and its ingredients are not more than minimally processed.<sup>5</sup>

In August 2005, FSIS updated the text of the 1982 natural policy to, among other things, explicitly permit the use of sodium lactate in products bearing natural claims.<sup>6</sup> More specifically, the 2005 text

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<sup>3</sup> 9 CFR Part 317.

<sup>4</sup> FSIS Office of Policy, Program and Employee Development, *Food Standards and Labeling Policy Book*, at 2 (August 2005, as amended December 2006), found at [http://www.fsis.usda.gov/Regulations & Policies/Labeling Policies/index.asp](http://www.fsis.usda.gov/Regulations%20&%20Policies/Labeling%20Policies/index.asp). At the December 12, 2006 public meeting on "Product Labeling: Definition of the Term 'Natural,'" FSIS stated that "policy guidance would provide a helpful and transparent way for the Agency to set up factors that the Agency considers in making judgments about whether particular types of labeling are truthful and non-misleading. Usually we develop a policy guide when we see a trend developing in the marketing of products with certain labeling features, statements or claims that have not been explicitly addressed by the Agency in its regulations. The guidance is intended to set out how the statutory provisions and the regulations on labeling apply to the developing trend and to provide consistent and timely advice to help manufacturers develop labeling that could be improved by the Agency." Transcript of December 12, 2006 Public Meeting on *Product Labeling: Definition of the Term "Natural,"* Statement of Dr. Robert C. Post, at 20.

<sup>5</sup> 71 Fed. Reg. at 70503. Minimal processing may include: (a) Those traditional processes used to make food edible or to preserve it or to make it safe for human consumption, e.g., smoking, roasting, freezing, drying, and fermenting, or (b) those physical processes that do not fundamentally alter the raw product or that only separate a whole, intact food into component parts, e.g., grinding meat, separating eggs into albumen and yolk, and pressing fruits to produce juices. Relatively severe processes, e.g., solvent extraction, acid hydrolysis, and chemical bleaching, would clearly be considered more than minimal processing. *Id.*

<sup>6</sup> 71 Fed. Reg. at 70504.

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read: “[n]ote . . . sodium lactate (from a corn source) . . . [is] acceptable for ‘all natural’ claims.”<sup>7</sup> Please note that FSIS interpreted this reference to sodium lactate as also encompassing potassium lactate. In practice, the agency systematically approved the natural labeling of products containing sodium lactate or potassium lactate at levels under 2 percent. The August 2005 natural policy did not explicitly prohibit or even discuss antimicrobial effects at this level.

It has been recognized that the August 2005 natural policy revision was not policy change; rather, it was a reflection of FSIS’ long-standing interpretation of its original 1982 natural policy and its numerous prior label approval decisions which permitted sodium, calcium, and potassium lactate as flavors in products labeled “natural.” FSIS itself has indicated that:

[s]ince 1982, FSIS has modified the . . . [1982 natural policy] on occasion to make it consistent with prevailing policies, to reflect case-by-case decisions made by the Agency, and to update references to the regulations. In August 2005, FSIS modified the guidance by acknowledging that sugar, sodium lactate from a foreign source, and natural flavorings from oleoresins or extractives could be acceptable for products bearing natural claims. These modifications were simply intended to record decisions about these ingredients that the Agency has made over several years in improving labels bearing natural on a case-by-case basis.<sup>8</sup>

Moreover, unlike FSIS’ recent unilateral change to the August 2005 natural policy, which we understand followed non-public discussions, the August 2005 revision was not the result of a petition or other similar effort by manufacturers or users of sodium lactate or potassium lactate – rather, it was an agency-driven effort aimed at clarifying to the public its historical interpretation of the 1982 natural policy.

## **B. The Hormel Petition**

On October 9, 2006, Petitioner submitted a petition to FSIS requesting the agency to initiate rulemaking procedures to amend 9 CFR § 317 and 9 CFR § 381.129 to codify the definition of “natural” and clarify the circumstances under which it may be used on the label of meat or poultry products. The Petition reiterates that a meat or poultry product should not bear a natural label unless: (1) it does not contain artificial flavorings, artificial coloring ingredients, other artificial or synthetic ingredients, or chemical preservatives, and (2) it is not more than minimally processed. In addition, unlike the current FSIS natural policy that only prohibits “chemical preservatives,” the

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<sup>7</sup> FSIS *Food Standards and Labeling Policy Book*, at 117.

<sup>8</sup> Transcript of December 12, 2006 Public Meeting on *Product Labeling: Definition of the Term ‘Natural,’* Statement of Dr. Robert C. Post, at 24-25 (emphasis added).

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Petition seeks to prohibit “any substance, either natural or chemical, which serves to retard product deterioration as a result of microbial action.”<sup>9</sup>

The Petition explicitly opposes the August 2005 natural policy and the use of sodium lactate in natural products. Petitioner argues that this allowance is inconsistent with the prohibition on chemical preservatives and that it creates inconsistencies that confuse and misinform consumers.<sup>10</sup> Citing the likely length of any potential rulemaking process, the Petition requested that FSIS issue interim guidance and unilaterally revise the August 2005 natural policy to prohibit sodium lactate in products labeled “natural.”<sup>11</sup> In addition to filing the Petition, we understand the Petitioner actively lobbied officials to encourage them to adopt the Petition.

We note that the Petition does not present evidence of consumer confusion or concern regarding the use of potassium lactate in a product bearing the natural label. In this regard, it would appear that the Petition is aimed at gaining a competitive advantage in the natural market by seeking an exclusive right to use the word “natural” for product processed under its “high-pressure” technology.<sup>12</sup>

### C. FSIS Response to Hormel Petition and Current Status of the Natural Claim

In response to the Petition, FSIS: (1) published a December 5, 2006 notice and request for comments on the Hormel petition; (2) held a public hearing on December 12, 2006 to discuss the natural issue; and (3) stated that it would initiate rulemaking on the definition of “natural.”<sup>13</sup>

FSIS, however, inappropriately and unilaterally revised the August 2005 natural policy in December 2006 (without clearance from OMB or any opportunity for public input) out of concern that the use of sodium, calcium, and potassium lactate may conflict with the meaning of natural if they have a preservative effect at the levels of use associated with flavoring. The revised policy now notes that the reference to sodium lactate (from a corn source) has been removed from the guidance on natural claims because the agency has “recent[ly]” been provided with information indicating “that sodium

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<sup>9</sup> Hormel Petition, at 13 (emphasis added).

<sup>10</sup> Hormel Petition, at 10.

<sup>11</sup> Hormel Petition, at 14.

<sup>12</sup> Carole Sugarman, “Natural” Definition For Meat and Poultry Causes Confusion, 48 Food Chemical News at 23-24 (Dec. 18, 2006). See also, Kiger, *Post-Bulletin*, December 13, 2006; McClatchy, *Washington Bureau*, December 5, 2006; Adamy, *Wall Street Journal*, February 17, 2005.

<sup>13</sup> 71 Fed. Reg. at 70503.

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lactate, potassium lactate, and calcium lactate provide an antimicrobial effect at levels that have been regulated as providing a flavoring effect.”<sup>14</sup>

In addition, FSIS also sent letters to various companies (including Farmland) that have existing label approvals for natural products containing sodium lactate or potassium lactate as flavoring agents. In these letters, FSIS threatened to revoke the approvals unless the companies established that the sodium lactate and/or potassium lactate have no microbial effect on the finished product nor any impact on shelf life or use-by dating. The letters convey a sixty-day deadline for processors to demonstrate no microbial affect or shelf life extension. FSIS subsequently sent letters indicating that it was not necessary to present data on the microbial effect of potassium lactate, if companies presented data demonstrating that the shelf life or use-by date for products containing potassium lactate was the same as the shelf life or use-by date for products that did not contain potassium lactate.

### **III. Sodium Lactate and Potassium Lactate Are Appropriately Permitted in Food Products Labeled “Natural”**

Farmland believes sodium lactate and potassium lactate are natural ingredients and should qualify as “natural flavors,” particularly when used at levels under 2 percent. FSIS regulations regard flavoring as the primary function of potassium and sodium lactate at levels under 2 percent, and the agency should not disregard this regulatory framework when evaluating these issues. That a natural flavor has both flavoring and preservative functions should not preclude its use in natural products. Moreover, sodium and potassium lactates should not be deemed “chemical preservatives” under the terms of the FSIS natural policy.

#### **A. Lactates are Natural Ingredients**

Sodium lactate and potassium lactate, the sodium and potassium salts of lactic acid,<sup>15</sup> are natural ingredients. Lactic acid is produced naturally in foods such as cheese, pepperoni, sour dough bread and many others by the action of lactic acid starter cultures on the sugars that are naturally present in the food products.<sup>16</sup> The production of the lactic acid increases the acidity of the product, flavoring the product and protecting the product from early spoilage. This same lactic acid and the lactate

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<sup>14</sup> FSIS *Food Standards and Labeling Policy Book*, at 117.

<sup>15</sup> 52 Fed. Reg. 10884 (April 6, 1987).

<sup>16</sup> Applegate Farms, *What is Sodium Lactate?*, found at <http://www.applegatefarms.com/A556B4/NutrInfo.nsf/81647a0fea1a2f0485256a12005d283d/be281aa64774935285256a12006626cf?OpenDocument>. See also, *The Physiology and Biochemistry of Muscle as a Food*, 2 (E.J. Briskey, R.G. Cassens, and B.B. Marsh eds., U. Wisc. Press 1970).

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salts of lactic acid naturally occur in all animal and human tissues.<sup>17</sup> Sodium and potassium lactate also occur naturally in the metabolic functions of mammalian species.<sup>18</sup>

Sodium lactate is produced by the natural fermentation of the sugars from corn or beets. These sugars are fermented with lactic acid starter culture, similar to those used for cheese or yogurt production. The fermented solution is mixed with caustic soda to form sodium lactate in the same way soymilk is mixed with calcium sulfate to form tofu.<sup>19</sup> Potassium lactate is produced in the same general manner and has the same properties as sodium lactate, but starts with potassium instead of a sodium base. Potassium lactate is often used in reduced sodium or sodium-free products. A substance may have an antimicrobial effect but still remain natural. Salt, sugar, vinegar and spices are all additive ingredients, yet they certainly do not automatically render the foods to which they are added unnatural.

**B. FSIS Should Adhere to its Policy of Allowing the Use of Sodium Lactate and Potassium Lactate As Natural Flavors in Natural Products in Levels Up to 2 Percent**

FSIS and FDA extensively regulate sodium and potassium lactate and have permitted their use as flavor enhancers or flavoring agents in food products. FSIS explicitly permits the use of sodium lactate and potassium lactate in various meat and poultry products as: (1) flavor enhancers and flavoring agents in meat and poultry products at levels not to exceed 2 percent; and as (2) antimicrobials in meat and poultry products at levels up to 4.8 percent.<sup>20</sup> The FSIS regulation establishing the 4.8 percent antimicrobial level does not explicitly or implicitly affect the classification of potassium lactate and sodium lactate as flavoring agents or flavor enhancers if they are used at up to the 2 percent level.

Sodium lactate and potassium lactate are generally recognized as safe ("GRAS") by FDA for use as emulsifiers, flavor enhancers, flavoring agents, adjuvants, humectants, and pH control agents at levels not to exceed current good manufacturing practice.<sup>21</sup>

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<sup>17</sup> *Id.* See also L. Stryer, *Biochemistry* (2nd ed., W.H. Freeman and Co. 1981).

<sup>18</sup> 52 Fed. Reg. at 10884.

<sup>19</sup> Applegate Farms, *What is Sodium Lactate?*, found at <http://www.applegatefarms.com/A556B4/NutrInfo.nsf/81647a0fea1a2f0485256a12005d283d/be281aa64774935285256a12006626cf?OpenDocument>.

<sup>20</sup> 9 CFR § 424.21(c) (emphasis added).

<sup>21</sup> 21 CFR § 184.1768; 21 CFR § 184.1639 (emphasis added).



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Sodium lactate and potassium lactate are not artificial or synthetic ingredients, but are minimally processed natural flavors. Both FSIS and FDA define natural flavor as:

[t]he essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate, or any product or roasting, heating or enzymolysis, which contains the flavoring constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or any other edible portion of a plant, meat, seafood, poultry, eggs, dairy products, or fermentation products thereof, whose primary function in food is flavoring rather than nutritional.<sup>22</sup>

Sodium lactate and potassium lactate from corn fall squarely within the definition of natural flavor since they are essentially salts derived through fermentation from a natural ingredient - corn. In addition, fermentation is considered “minimal processing” and expressly allowed by FSIS’ natural policy. Accordingly, sodium and potassium lactates are appropriately used as natural flavors in products labeled “natural.”

**C. FSIS Has Classified Flavoring As the Primary Function of Sodium Lactate and Potassium Lactate at Less Than 2 Percent, While Recognizing That They Have Both a Flavor and Preservative Effect**

FSIS first approved sodium lactate and potassium lactate in 1993 for their flavoring capabilities (when used at up to a 2 percent level),<sup>23</sup> and only subsequently approved sodium lactate and potassium lactate in 2000 for their antimicrobial capabilities (when used at up to a 4.8 percent level).<sup>24</sup> In so doing, FSIS has created a regulatory framework for evaluating the primary and secondary effects of the lactates. Specifically, the agency considers flavoring to be the primary function of sodium lactate and potassium lactate when used at up to 2 percent, and the primary function of sodium lactate and potassium lactate when used between a 2 to 4.8 percent level to be an antimicrobial.

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<sup>22</sup> 9 CFR § 317.2(f)(1)(i)(B); 21 CFR § 101.22(a)(3).

<sup>23</sup> 58 Fed. Reg. 4067 (January 13, 1993). In the FSIS rulemaking establishing the 2 percent flavoring level, commenters recognized how “the flavoring enhancing properties of sodium lactate add significantly to the flavor of meat and poultry products.” The petitioner who requested FSIS to allow the use of potassium lactate and sodium lactate as flavor enhancers and flavoring agents in cooked meat and poultry products submitted data clearly demonstrating that “sodium lactate has the technical effect of a flavoring by contributing to the salty taste of products.” 58 Fed. Reg. at 4068. Although the petitioner did not present figures on the levels of use necessary to achieve saltiness of potassium lactate, it estimated that it would be the same as sodium lactate. FSIS explicitly agreed with this estimate concerning potassium lactate “due to FDA’s . . . affirm[ation] that sodium and potassium salts of lactic acid will perform the technical effects of flavor enhancer and flavoring agent.” *Id.*

<sup>24</sup> 65 Fed. Reg. 3121 (January 20, 2000).

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In fact, when establishing the 2 percent flavoring standard, FSIS acknowledged that “[p]otassium lactate and sodium lactate may be considered as having ‘antimicrobial’ properties,” but noted that the FSIS “allows the use of certain substances with antimicrobial properties but classifies them by their primary functions.”<sup>25</sup> This discussion clearly establishes that FSIS in fact: (1) considers the primary function of sodium lactate and potassium lactate used in meat and poultry products at levels up to 2 percent to be flavoring; and that (2) any antimicrobial effect that impacts shelf life under the 2 percent level to be a secondary function.

FSIS’ newly formed disregard of its primary classification of sodium lactate and potassium lactate as flavoring agents and flavor enhancers is arbitrary and capricious. If FSIS considers flavoring to be the primary function of sodium lactate and potassium lactate at the 2 percent level, then FSIS cannot override this conclusion in the context of its natural policy. In so doing, FSIS is implicitly amending the existing regulation and making decisions regarding the characterization of ingredients (and consequently processes) by their primary and secondary effects in an *ad-hoc* manner. Given the established agency position that flavoring is the primary function of sodium lactate at up to 2 percent, it is arbitrary and capricious and an abuse of discretion for the agency to disregard this position when evaluating the appropriateness of sodium lactate and potassium lactate at the agency established flavoring levels in products that carry a “natural” label.

Moreover, although there has been an assertion that the FSIS was not aware of the antimicrobial effects of potassium lactate and sodium lactate at levels that have been regulated as providing a flavoring effect, the regulatory history of the rulemakings authorizing sodium lactate and potassium lactate for use as flavoring agents suggests otherwise. FSIS’ December 2006 revision to the natural policy in response to the Hormel Petition states, in pertinent part, that:

recent information provided to FSIS . . . indicates that sodium lactate, potassium lactate, and calcium lactate provide an antimicrobial effect at levels that have been regulated as providing a flavoring effect. Therefore, regardless of whether it can be shown that any form of lactate is from a natural source and is not more than minimally processed, the use of lactate (sodium, potassium, and calcium) may conflict with the meaning of “natural” because it may be having a preservative effect at levels of use associated with flavoring. Thus, listing “sodium lactate (from a corn source)” in the previous entry may have been in error . . .<sup>26</sup>

The agency, however, has been aware of the antimicrobial effects of sodium lactate and potassium lactate as far back as 1993. As noted above, the 1993 rulemaking that established the use of 2 percent sodium lactate and potassium lactate as flavors is characterized by an active dialogue about

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<sup>25</sup> 58 Fed. Reg. at 4069.

<sup>26</sup> FSIS *Food Standards and Labeling Policy Book*, at 117 (emphasis added).

the various effects and purposes of these ingredients. For example, one commentator opposed the proposed rule because it believed that the purpose of “lactate salts” was for food safety through microbiological control, with a secondary effect on flavor, while another argued that FSIS should either withdraw the rulemaking or revise it “to recognize that lactates are being used for their preservative characteristics . . .”<sup>27</sup> As noted above, the agency rejected these comments, noting that it classifies substances according to their primary function, and proceeded to codify the primary use of up to 2 percent sodium lactate and potassium lactate for flavor.

Given this active discussion as far back as 1993, the assertion that the agency was unaware of the secondary effects of sodium lactate and potassium lactate when it issued the August 2005 policy change is not persuasive.

In any event, any preservative effect resulting from the use of this natural ingredient at the flavoring level should not preclude its use in natural products, particularly since the agency has long been aware of this dual function.

**D. The Dual Functionality or Secondary Preservative Effect Does Not Preclude the Use of Lactates in Natural Products**

Since its inception, the FSIS policy for natural claims has allowed the use of ingredients and minimal processing activities that affect the shelf life of a product. The two principal tenets of the FSIS natural claim not changed since 1982: (1) the product may not contain any artificial flavor or flavoring, coloring ingredient, or chemical preservative (as defined by 21 CFR § 101.22), or any other artificial or synthetic ingredient; and (2) the product and its ingredients may not be more than minimally processed.

Numerous natural ingredients have an impact on shelf life. As noted above, salt, for example, is added to products and extends shelf life. Vinegar also extends shelf life. Certain essential oils or antioxidants that are natural ingredients may also affect shelf life. The natural policy also expressly allows “those traditional processes used to make food edible or to preserve it or to make it safe for human consumption, *e.g.*, smoking, roasting, freezing, drying, and fermenting.”<sup>28</sup>

Substances that have an effect on the shelf life of a product are not categorically ineligible for inclusion in a natural product. It is indisputable that virtually anything that impacts the condition of the product will have an impact on its shelf life. The mere fact that potassium and sodium lactates have a dual function or secondary antimicrobial effect does not justify their exclusion from the natural policy.

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<sup>27</sup> 58 Fed. Reg. at 4069.

<sup>28</sup> FSIS *Food Standards and Labeling Policy Book*, at 116 (emphasis added).

### E. Sodium Lactate and Potassium Lactate Are Not “Chemical Preservatives”

Lactates are not “chemical preservatives” as defined in FDA regulations (21 CFR § 101.22), which defines a chemical preservative to mean:

any chemical that, when added to food, tends to prevent or retard deterioration thereof, but does not include common salt, sugars, vinegars, spices, or oils extracted from spices, substances added to food by direct exposure thereof to wood smoke, or chemicals applied for their insecticidal or herbicidal properties.

Based upon this definition, FDA regulations do not classify sodium lactate or potassium lactate as “chemical preservatives” or any other type of food preservatives. As noted above, FDA has generally recognized as safe sodium lactate and potassium lactate for use only as emulsifiers, flavor enhancers, flavoring agents, adjuvants, humectants, and pH control agents at levels not to exceed current good manufacturing practice. Even the FDA Investigations Operations Manual’s (“IOM”) Food Additive Status List fails to classify potassium lactate and sodium lactate as chemical preservatives.<sup>29</sup> In short, nowhere in FDA regulations is potassium lactate listed as a chemical preservative.

Moreover, FSIS itself has acknowledged that “potassium lactate and sodium lactate are not classified as ‘preservatives’” by the Food and Drug Administration.<sup>30</sup> That conclusion holds true to this day. Since FSIS recognized that FDA has not classified potassium and sodium lactate as preservatives, and FDA has not in fact classified potassium and sodium lactate as “chemical preservatives,” it is difficult to see how FSIS can reverse course and change its longstanding policy allowing the use of lactates in all natural products by claiming that they are “chemical preservatives.”

The conclusion that sodium lactate and potassium lactate are not “chemical preservatives” under 21 CFR § 101.22 for purposes of the natural labeling policy is supported by the underlying terms of the policy itself and by FSIS regulations. The language in FSIS’ natural policy is intended for artificial or synthetic ingredients - not ingredients that are simply “chemical.” In the broadest sense, all matter has a chemical nature. To apply the term “chemical preservative” to any ingredients that have a preservative effect, including natural ingredients that have been used for thousands of years, is

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<sup>29</sup> FDA Center for Food Safety and Applied Nutrition, Office of Food Additive Safety, *Food Additive Status List*, (July, 2006), found at <http://www.cfsan.fda.gov/~dms/opa-appa.html#ftnP>. The Food Additive Status List organizes additives found in many parts of 21 CFR into one alphabetized list that includes use limitations and permitted tolerances for each additive.

<sup>30</sup> 58 Fed. Reg. at 4069 (emphasis added). The Food Chemical Codex similarly lists the functions of sodium lactate and potassium lactate as emulsifiers, flavor enhancers, flavoring agents, adjuvants, humectants, and pH control agents. The Food Chemicals Codex has never formally listed sodium lactate or potassium lactate as chemical preservatives.

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nonsensical. Lactates, which are members of the salt family, are natural ingredients, perfectly appropriate for use in a natural product.

The Petition implicitly recognizes this distinction by suggesting that additional language should be added to the natural policy. Specifically, the Hormel Petition suggests that the natural policy be revised to state:

[b]eyond the definition of “chemical preservative” found in 21 CFR 101.22, it is intended that any substance, either natural or chemical, which serves to retard product deterioration as a result of microbial action would not be allowed in products which carry an all natural claim.<sup>31</sup>

We believe it is fair to say that by “chemical preservative,” it was intended that ingredients of an artificial or synthetic nature be barred.

The revision proposed by Hormel would effectively prohibit the use of any natural ingredients (including salt, vinegar, and spices) that may also have preservative effects in products labeled “natural,” and deny manufacturers the option of using natural ingredients to promote food safety.

#### **IV. Change in the August 2005 Natural Policy is Arbitrary and Capricious And Is Regulatory Action That Must Occur Through Notice and Comment Rulemaking**

If the agency is going to establish a policy that ingredients or minimal processing cannot have a secondary effect on shelf life, or to define what the limit of that effect can be, then FSIS must take this action via notice and comment rulemaking in which the full range of ingredients and practices are evaluated and the public is provided a full and fair opportunity to comment.

The agency’s recent change to its August 2005 natural policy is arbitrary and capricious and an abuse of discretion. Moreover, when coupled with its demand letters, the agency’s actions constitute rulemaking subject to the notice and comment requirements of the APA. Under the agency’s longstanding policy, sodium lactate and potassium lactate were approved for use at the agency established flavoring levels in products labeled “natural.” Under its recent unilateral revision to this policy, FSIS effectively established a new mandatory requirement. Food manufacturers cannot use potassium lactate if the food products carrying a natural label have a sell-by or shelf life date that is not the same as a product that does not have this ingredient.

The FSIS rationale for reversing its longstanding agency policy does not appear to be well-formed. The agency has published regulations establishing that flavoring is the primary effect of potassium lactate at levels up to 2 percent, a regulation that is effectively or implicitly amended by the recent

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<sup>31</sup> Hormel Petition, at 13 (emphasis added).

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change in the natural policy. The agency also claims that the Hormel Petition presents new information and that the agency was unaware that the lactates have a preservative effect at the flavoring levels, when in fact a review of the agency's regulatory history makes plain that the agency has been aware of such effects since the time that it established standards allowing the use of lactates as a flavor.

FSIS has fundamentally changed the rules under which a product can be labeled "natural," and its actions go well beyond a general statement of agency policy. The revised policy, coupled with the demand letters, make clear that the agency is imposing a new standard that will be applied to all existing and future products, and that the agency does not retain any discretion to allow products to bear the natural label if they contain certain ingredients that have the dual or secondary effect of prolonging shelf life or use-by dates beyond that of a product that does not contain the ingredients.

We note that the FSIS-initiated August 2005 natural policy revision did not require rulemaking because it was not a policy change; rather, it was a reflection of FSIS' long-standing interpretation of its original 1982 natural policy and its numerous prior label approval decisions permitting sodium, calcium, and potassium lactate as flavors in products labeled "natural." FSIS' recent unilateral change to this August 2005 natural policy, however, is a dramatic departure from existing agency practice and prior approval decisions. That this was done without public input and at the request of a competitor with a unique position in the market is a very real concern.

The August 2005 natural policy revision did not establish a new and binding norm with which companies must comply, nor did it require any labeling changes by a regulated entity. In contrast, the recent December 2006 unilateral change abruptly reverses the existing policy upon which Farmland and others have reasonably relied, fundamentally changes the rules under which a product can be labeled "natural," and requires immediate and costly changes in established processes. FSIS is effectively mandating that Farmland, for example, relabel all products currently bearing an FSIS-approved natural label if the products containing lactate have a shelf life or use-by date that is different from products that do not contain lactate. This direct and immediate impact on Farmland's rights and obligations evidences that FSIS is in fact establishing new and binding norms. Product that had previously been allowed to carry a natural label would now be considered mislabeled.

Farmland believes FSIS' actions are not based on protecting the public from false or misleading labeling but rather is an economic regulation that effectively distorts the market and provides the Petitioner with a competitive advantage. In essence, FSIS would allow products with lactate for flavor to be labeled "natural," so long as they are not sold beyond the shelf life of products that do not contain lactate. There is either something inherently wrong with selling as "natural" a product that has the lactates, or there is not. It is arbitrary and capricious for FSIS to conclude otherwise.

FSIS should therefore immediately reinstate the August 2005 natural policy until it has had a chance to more fully deliberate on the issue.

## V. FSIS Should Maintain a Level Playing Field Pending Rulemaking

Although FSIS itself recognizes that rulemaking may be the proper forum for resolving issues related to its natural policy, it nevertheless made changes to the policy without full opportunity for public debate and comment. In its December, 2006 notice regarding the Petition in which it announced a public meeting on the natural issue, FSIS stated that:

The Agency has come to recognize, based on the controversy that has arisen about “natural” in recent months, that there is significant disagreement about aspects of the August 2005 policy modification, particularly the recognition of sodium lactate as an ingredient that could be included in products that bear a “natural” claim. The Agency has received information that raises questions about when, and if, a food to which sodium lactate has been added would be fairly characterized as “natural.” The Agency has come to believe that this question, like numerous others alluded to in this document, is best resolved through a rulemaking process.<sup>32</sup>

Farmland appreciates that there may be new questions that warrant rulemaking. As noted above, as new technologies emerge, new issues arise. For example, some consumers might find Petitioner’s high pressure processing to be more than minimally processed and unnatural. High-pressure processing involves:

[U]sing extremely high pressure, up to 87,000 pounds per square inch, to kill bacteria in the food. It is similar to the conditions at the bottom of the deepest part of the ocean, magnified five-fold, Dr. James Marsden, a food scientist at Kansas State University and science liaison of the North American Meat Processors Association, Reston, Va., explains. “The pressure is so great down there that few living things can survive.” The pressure of 87,000 psi is approximately equal to three full-grown elephants standing on a beam with the weight of the beam centered on the face of a dime.<sup>33</sup>

Like sodium lactate, Petitioner’s high-pressure processing helps to extend shelf life. As with sodium lactate, FSIS has permitted products that have undergone high-pressure processing to bear the natural label. A notice and comment rulemaking process would provide an opportunity to explore such issues and to make a well-reasoned decision on the proper use of the natural claim.

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<sup>32</sup> 71 Fed. Reg. at 70504.

<sup>33</sup> Harris, Chris, *The Big Squeeze*, Meat Processing Magazine (February, 2006), found at [http://www.meatnews.com/mp/northamerican/dsp\\_article\\_mp.cfm?artNum=444](http://www.meatnews.com/mp/northamerican/dsp_article_mp.cfm?artNum=444).

The FSIS action related to the recent change in the rule book and issuance of the letter did not follow any public process or open discussion of the issues, nor was it the result of public criticism by consumers who felt misled by all natural labels on products treated with lactates. Rather, it appears the revision of the August 2005 natural policy was done solely in response to the Petition.

FSIS' unilateral change to the August 2005 policy has immediately created an unfair business environment and established a competitive advantage for one company. The change will have a significant economic impact on Farmland and other affected companies. Unlike the unilateral change to FSIS' natural policy in response to the Hormel Petition, the August 2005 natural policy update allowing the use of sodium lactate in natural products codified decisions that had been made over several years. Farmland and many other manufacturers and companies have relied on those decisions, the subsequent August 2005 natural policy, and existing label approvals. They have not only created product lines and manufacturing processes based on that policy, but they have also entered into contracts with suppliers and customers and have product in inventory that carry labels approved under that policy.

Given the complexity of the issues and the interests at stake, FSIS must retain the August 2005 natural policy while it conducts notice and comment rulemaking on the scope of the natural label claim and the standards that will be used to evaluate whether technologies and ingredients are natural. In this rulemaking, Farmland would note that, prior to the unilateral revision of the August 2005 policy, the agency decision-making process for allowing all natural claims had worked for the agency, the regulated community, and consumers, with all parties having confidence in the flexible, case-by-case decision making of the agency. Farmland would encourage the agency to retain such flexibility, while providing clarity and certainty for manufacturers, producers, and consumers.

#### **VI. The Change in the August 2005 Natural Policy is a Significant Guidance Document That Requires Review by OMB and Opportunity for Public Comment**

The agency's new "natural" definition is a significant guidance document that requires review by OIRA at OMB.

The FSIS policy for natural label claims is contained in the FSIS Food Standards and Labeling Policy Book. The Policy Book expressly states that it "is intended to be guidance to help manufacturers and prepare product labels that are truthful and not misleading."<sup>34</sup> When FSIS issued the new natural policy, FSIS republished the entire Food Standards and Labeling Policy Book. Since the book applies to the entire meat and poultry industry, it has an annual economic impact of well-over \$100 million, the threshold for an economically significant guidance document under OMB's recent

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<sup>34</sup> FSIS *Food Standards and Labeling Policy Book*, at 2.



Final Bulletin for Agency Good Guidance Practices.<sup>35</sup> It is also a significant guidance document that requires OMB review under Executive Order 12866.

Even if viewed separate from the entire Food Standards and Labeling Policy Book, FSIS' creation of a new labeling definition for natural claims is a significant guidance document under Executive Order 12866. The new definition of a natural claim under FSIS jurisdiction "may be reasonably anticipated to . . . adversely affect in a material way a sector of the economy, productivity, [and] competition."<sup>36</sup> The new FSIS policy "may [also] be reasonably anticipated to [c]reate serious inconsistency . . . with an action planned by another agency" and "[r]aise novel legal or policy issues . . ."<sup>37</sup>

The consumer market for natural foods is rapidly growing and carries a price premium. The definition, scope, and integrity of this market are important to the overall food industry. As noted above, companies have invested millions to develop, produce, and market natural products in reliance on prior decisions by FSIS and the August 2005 natural definition. Radically revising that definition to preclude the ability of those companies to label their products as natural will adversely affect a sector of the economy and its productivity. In addition, because the new FSIS definition appears to be in response to the petition of one competitor that uses an alternative technology, and would restrict competitors while allowing the alternative technology, the new definition adversely and materially affects competition.

As FSIS noted in its rulemaking establishing lactates as flavoring agents, FDA has not determined sodium lactate or potassium lactate to be preservatives. FSIS is now, however, asserting that sodium lactate and potassium lactate (used for flavoring purposes) are "chemical preservatives" under FDA regulations. This is a fundamental inconsistency between two Federal agencies that may warrant OMB intervention in order to ensure consistent Federal policy regarding natural label claims. Moreover, as noted below, FSIS actions may also run afoul the First Amendment by restricting truthful and non-misleading commercial speech.

With respect to OMB jurisdiction and authority to review significant guidance documents, it should be noted that the recent revisions to Executive Order 12866 by Executive Order 13422 of January 18, 2007, in which OMB is giving express authority to review significant agency guidance, merely

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<sup>35</sup> Office of Mgmt. & Budget, Executive Office of the President, OMB Bull. No. 07-02, *Final Bulletin for Agency Good Guidance Practices*, reprinted in 72 Fed. Reg. 3432, 3435 (Jan. 25, 2007).

<sup>36</sup> Exec. Order No. 12866, 58 Fed. Reg. 51735 (Oct. 4, 1993), as amended by Exec. Order No. 13258, 67 Fed. Reg. 9385 (Feb. 28, 2002) & Exec. Order No. 13422, 72 Fed. Reg. 2763 (Jan. 23, 2007) (*see* Sec. 3(f)(1)).

<sup>37</sup> *Id.*, at Sec. 3(f)(2), (f)(4).

codified a long-standing practice.<sup>38</sup> Farmland believes that OMB has consistently claimed and exercised jurisdiction to review significant guidance documents issued by Federal agencies, including USDA agencies. The fact that this authority was only recently codified in Executive Order 12866 does not relieve USDA of its obligation to submit significant guidance documents to OMB for review.

It should also be noted that one of the authorities for OMB jurisdiction over agency guidance is the Information Quality Act.<sup>39</sup> In this regard, FSIS has arguably violated the Information Quality Act by making decisions on the basis of incomplete data. That is, FSIS is acting solely in response to information received in a petition from a competitor. In so doing, FSIS has reversed longstanding policy, ignored its own regulatory history, and has deprived the public of the opportunity to explore these issues in an open and transparent manner. The proper determination of when products and processes that have multifunctional effects on food should be allowed to carry a natural label is a complex question. While the agency recognizes this complexity, it would appear the agency acted without fully weighing all of the evidence in an open and transparent forum.

## **VII. FSIS Actions Implicate the First Amendment and Commercial Free Speech**

FSIS' change to the August 2005 natural policy also unfairly restricts commercial free speech. FSIS authority with respect to food labels is limited to protecting against any labeling that is false or misleading in any particular. Since sodium lactate and potassium lactate are natural flavors that are minimally processed and being used at the levels established for flavoring, a natural label on a product that has been treated with up to 2 percent sodium lactate or potassium lactate is not false or misleading. There is very strong consumer interest in natural products and the natural label claim is commercial speech protected by the First Amendment.

Under existing First Amendment jurisprudence, regulation of lawful and non-misleading commercial speech is constitutional only if: (1) the government interest justifying the restriction on commercial speech is substantial; (2) the government regulation directly advances the governmental interest asserted; and (3) the government regulation is no more extensive than necessary to serve the proffered interest.<sup>40</sup>

By prohibiting the use of the natural claim on the label of a product containing sodium lactate or potassium lactate for flavoring purposes, FSIS is effectively banning truthful and non-misleading commercial speech through its mandatory pre-market label approval process. Even if there is some

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<sup>38</sup> Exec. Order No. 12866, 58 Fed. Reg. 51735 (Oct. 4, 1993), *as amended by* Exec. Order No. 13422, 72 Fed. Reg. 2763 (Jan. 23, 2007)(*see* Sec. 9).

<sup>39</sup> 44 USC §§ 3504(d)(1), 3516.

<sup>40</sup> *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557 (1980).

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basis to address the use of the "natural" claim on such products, FSIS' position and policy in this matter are more restrictive than necessary to address any perceived or potential governmental interest and constitute a prior restraint on lawful, truthful, and non-misleading commercial speech by Farmland to its customers.

There have been many developments in recent years regarding the application of the First Amendment to commercial speech, including in the labeling and health and safety context. If necessary, Farmland stands ready to elaborate fully upon the underlying constitutional analysis to support its conclusion.

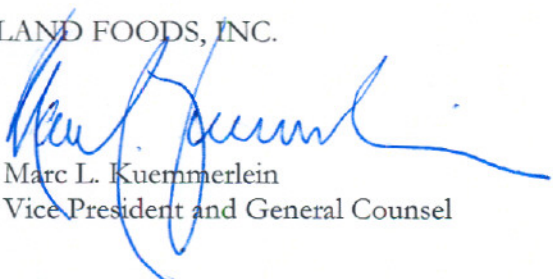
### VIII. Conclusion

We maintain that it is not in the public interest that food manufacturers be barred from using natural ingredients solely because these ingredients enhance food safety. Nor is it appropriate that long-standing policies be changed based on the sole input of one competitor, particularly when the changes would give that competitor a unique advantage in the market. When these policy changes appear to be unsupported by legal or factual bases, it becomes compelling that the agency should examine its process and reconsider its course of action.

In light of the above, Farmland respectfully requests that: (1) FSIS maintain its August 2005 natural policy, including the allowance of the natural label on products containing sodium lactate and potassium lactate; and (2) any FSIS rulemaking on the definition of "natural" allow products containing lactate at levels up to 2 percent of formulation to be labeled "natural."

Sincerely,

FARMLAND FOODS, INC.

By:   
Vice President and General Counsel

cc: Steven D. Aitken, Acting Administrator, OIRA