

Phillip L. Minerich, Ph.D.

Vice President

Research & Development

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Hormel Foods Corporate Services, LLC

Research & Development

2 Hormel Place

Austin MN 55912-4935

Phone 507 434 6372

Fax 507 437 5117

Dr. Robert C. Post
Director, Labeling and Consumer Protection Staff
Food Safety and Inspection Service, USDA
1400 Independence Ave. SW
Suite 602, Annex
Washington, DC 20250

RE: Petition for the Issuance of a Rule Regarding Natural Label Claims

Dear Dr. Post:

The August 2005 change to the USDA Food Safety and Inspection Service (FSIS) Natural Policy renders the policy's guidance internally inconsistent and creates confusion regarding whether a meat or poultry product bearing a Natural claim may yet contain chemical preservatives and synthetic ingredients. Because the interests of consumer protection and confidence require clarity and certainty in the use of the word "natural" on product labeling, Hormel Foods Corporation hereby submits this Petition, under 7 CFR 1.29 and 5 U.S.C. 553(e), for the Issuance of a Rule Regarding Natural Label Claims.

I. Action Requested

Hormel Foods Corporation requests the USDA Food Safety and Inspection Service 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 a meat or poultry product. Consistent with current longstanding policy and practice, 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. Issues of consumer confidence and consistency in labeling dictate that exceptions for specific chemical preservatives and synthetic ingredients should not be allowed.¹

¹ Consistent with 21 CFR 101.100(a)(3), the only exception that should be allowed are specific and unavoidable incidental additives or processing aids.

II. Background

Consumer interests in natural products are rising. Not surprisingly, manufacturers are seeking to establish marketing presence in this growing niche. Efforts by manufacturers to meet consumer preferences are generally applauded. Recent changes in the USDA FSIS's Natural Policy, however, provide inconsistent guidance which may provide loopholes that would allow manufacturers to manipulate exceptions in the Policy to confuse consumers and erode the meaning of the Natural label.

A. Prior Natural Policy

The original Natural Policy was issued over 23 years ago, on November 22, 1982. This prior Policy was consistent with consumer expectations and was easily understood and applied by industry and regulators alike.

The term "natural" may be used on labeling for meat and poultry products, provided the applicant for such labeling demonstrates 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.

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 which do not fundamentally alter the raw product and/or which 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.²

B. Current Natural Policy

In August 2005, the Policy was changed. The basic two-part requirement remains unchanged. It continues to prohibit chemical preservatives, artificial flavorings and colorants, and other artificial or synthetic ingredients and requires that products be

² Policy Memo 055 (Nov. 22, 1982).

minimally processed. The new Policy further provides additional guidance regarding the use of ingredients that have been more than minimally processed and differentiates “natural product” claims from “natural ingredient” claims.

Two new provisions of the Natural Policy, however, create inconsistency within the Policy and, consequently, the potential for consumer confusion and erosion of the significance of the natural claim. These provisions are (1) the acceptance of sodium lactate from a corn source for “all natural” claims and (2) the reference to the National Organic Policy for acceptable ingredients allowed for “all natural” claims.

The current Natural Policy provides:

The term “natural” may be used on labeling for meat and poultry products, provided the applicant for such labeling demonstrates that:

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

the product and its ingredients are not more than minimally processed.

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 which do not fundamentally alter the raw product and/or which 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. Thus, the use of a natural flavor or flavoring in compliance with 21 CFR 101.22 which has undergone more than minimal processing would place a product in which it is used outside the scope of these guidelines. However, the presence of an ingredient which has been more than minimally processed would not necessarily preclude the product from being promoted as natural. Exceptions of this type may be granted on a case-by-case basis if it can be demonstrated that the use of such an ingredient

would not significantly change the character of the product to the point that it could no longer be considered a natural product. In such cases, the natural claim must be qualified to clearly and conspicuously identify the ingredient, e.g., "all natural or all natural ingredients except dextrose, modified food starch, etc."

All products claiming to be natural or a natural food should be accompanied by a brief statement which explains what is meant by the term natural, i.e., that the product is a natural food because it contains no artificial ingredients and is only minimally processed. This statement should appear directly beneath or beside all natural claims or, if elsewhere on the principal display panel; an asterisk should be used to tie the explanation to the claim.

The decision to approve or deny the use of a natural claim may be affected by the specific context in which the claim is made. For example, claims indicating that a product is a natural food, e.g., "Natural chili" or "chili - a natural product" would be unacceptable for a product containing beet powder which artificially colors the finished product. "All natural ingredients" might be an acceptable claim for such a product.

Note: Sugar, sodium lactate (from a corn source), natural flavorings from oleoresins or extractives are acceptable for "all natural" claims.

This entry cancels Policy Memo 055 dated November 22, 1982.

See: 7 CFR NOP Final Report, part 205.601 through 205.606 for acceptable ingredients allowed for all natural claims.³

III. Argument

Agencies and citizens alike have long recognized the necessity of a clear definition of the word "natural" used on labeling claims. Consumers are confused as to the specific meaning, but are consistent in their assumptions that 'natural' products do not contain artificial or synthetic ingredients or preservatives.

The new FSIS Natural Policy does little to solve—and will likely only exacerbate—consumer confusion. Its far-reaching exemptions for certain artificial and synthetic

³ United States Department of Agriculture, Food Safety and Inspection Service, Office of Policy, Program and Employee Development, FOOD STANDARDS AND LABELING POLICY BOOK, Aug. 2005.

ingredients and preservatives swallow its purported prohibitions on such ingredients, rendering the Policy meaningless and eroding the meaning of the Natural claim.

A. Interests of Consumer Protection and Confidence Dictate Codification of the Natural Claim.

Agency recognition of the need for a clear definition controlling Natural claims and consequent attempts at formal rulemaking date back to the early 1980s. Recent citizens petitions filed with the Food and Drug Administration (FDA) underscore the continued need for codification of the Natural Claim.

1. Agencies have long recognized the need for a clear definition of “natural.”

The great consumer interest in a clear definition for “natural” label claims is demonstrated by over 20 years of rulemaking history. In the early 1980s, the Federal Trade Commission proposed to define “natural” foods as “those with no artificial ingredients and only minimal processing.”⁴ When the effort was subsequently abandoned in 1983, the FTC rationalized its inaction by noting its proposal concerned only advertising and trusting the consumer would be properly informed by product labeling.⁵ Commissioner Michael Pertschuk’s separate statement, however, voiced continued concern for consumer protection:

This abdication invites a free-for-all for deceptive health claims for food – claims which will cynically exploit and distort growing public concern with diet and health. Advertisers will continue to spend fortunes to promote high fat foods as healthful, highly processed foods as natural, and high calorie foods as “dietetic” or as miracle energy tonics.⁶

The next effort to define the term “natural” came from the Food and Drug Administration in 1989.⁷ As the agency noted, “The meaning and use of the term ‘natural’ on the label are of considerable interest to consumers and industry.” It further concluded “that uses of ‘natural’ claims are confusing and misleading to consumers and frequently breach the public’s legitimate expectations about their meaning.”⁸ Because of the consumer interest and widespread use of the term, FDA concluded that it should define the term. “FDA believes that if the term ‘natural’ is adequately defined, the

⁴ See 48 FR 23270-01.

⁵ *Id.* at 3270. “Thus consumers have ready access to much of the information covered in the food rule at the point of sale, where it is of most value to the decision to purchase.” *Id.*

⁶ *Id.* at 3271.

⁷ 54 FR 60421.

⁸ 56 FR 60421, 60466.

ambiguity surrounding use of the term that results in misleading claims could be abated.”⁹

In response to its advance notice of proposed rulemaking on this issue, FDA received 450 written comments addressing the terms “light”, “fresh” and “natural.” These comments almost universally agreed the FDA should act as quickly as possible to define these terms.¹⁰ A common concern noted the unregulated use of such descriptors resulted in consumer confusion. One comment noted the terms were “meaningless” and “primarily used as marketing tools rather than as guides for the health conscious consumer.”¹¹ By contrast, food industry representatives requested flexibility in the use of the descriptors.¹²

In 1993, however, citing resource limitations and other priorities, FDA abandoned its efforts to define “natural.” This was in spite of its continued belief that the term should be defined to avoid misleading consumers.¹³

2. A clear definition of “natural” will further consumer and industry interests.

a) Consumers continue to report confusion and call for rulemaking to define “natural.”

The agencies’ earlier acknowledgements of consumer confusion continue to be reaffirmed in consumer research and recent rulemaking petitions. General consumer interest in eliminating artificial ingredients and preservatives from their diets is on the rise. In 2001, only 8% of consumers checked food labels to determine the type and presence of preservatives in foods. By 2003, that number had increased dramatically, to 67%.¹⁴ On the other side of this interest in food labeling, however, is continued consumer confusion regarding the meaning of “natural.”¹⁵

Businesses and citizens groups have taken up the rulemaking gauntlet where the agencies left off. On February 28, 2006, the Sugar Association petitioned the FDA to

⁹ *Id.*

¹⁰ *Id.* at 60421-22.

¹¹ *Id.* at 60422.

¹² *Id.*

¹³ 58 FR 2302, 2407.

¹⁴ A. Elizabeth Sloan, Natural Foods Marketing Directions, *FOODTECHNOLOGY*, 14 (May 2003) [hereinafter “Natural Foods Marketing Directions”].

¹⁵ Care should be taken not to follow the lead of the National Organic Policy’s allowance of several different levels of “organic.” One source refers to organic as an “endangered category” as too many roles and different standards are causing consumers to lose trust. A. Elizabeth Sloan, New Product Showcases Sizzle with Sensational Ideas, *FOODTECHNOLOGY* 36-44, 40 (Sept. 2005) [hereinafter “New Product Showcases Sizzle”].

define "natural" for labeling claims.¹⁶ In support of the need for the rulemaking, the petition cites the "steady growth of consumer interest in natural and organic products" and stated that 63% of consumers prefer natural foods and vegetables.¹⁷ The petition requests the FDA to eliminate consumer confusion and minimize misleading claims by adopting strict regulations defining "natural." It further proposes that the FDA maintain consistency across the federal agencies by defining "natural" consistent with the current USDA policy.¹⁸ On March 13, 2006, the Center for Science in the Public Interest wrote in support of the petition.¹⁹

Consumer research continues to report confusion among consumers as to the meaning of "natural" and underscore the need for a clear definition. Survey results cited by the National Consumers League state focus group participants "unanimously agreed that there was a need for greater regulation of the 'natural' products regarding labeling, advertising, and industry standards." Consumers report interest in regulation that would define "natural" and develop standards to control the presence of preservatives, chemicals, additives and the degree of processing.²⁰

In the absence of a codified definition, the Center for Science in the Public Interest (CSPI) has resorted to enforcement action requests and threats of lawsuits to protect the integrity of "natural" claims. In July 2002, CSPI requested the FDA to take enforcement action against Ben & Jerry's Homemade Holdings, Inc. for false and misleading "all natural" claims on its ice creams. CSPI alleged the ingredients, partially hydrogenated soybean oil, alkalized cocoa powder, corn syrup, and corn syrup solids, were not natural.²¹

In May 2006, CSPI again took on a major food products manufacturer's "natural" claims. This time, CSPI alleged Cadbury Schweppes Plc d/b/a Cadbury Schweppes

¹⁶ Letter from Andrew C. Briscoe III, President and CEO, The Sugar Association to Docket Management Branch, Food and Drug Administration (Feb. 28, 2006) [hereinafter "Sugar Association Petition"].

¹⁷ *Id.* at 3-4.

¹⁸ Maintenance of consistency in the definition of "natural" across the federal agencies obviously is critical to eliminating consumer confusion. However, due to the problems with the current USDA Natural Policy described *infra*, it is respectfully submitted that FDA should not codify the current USDA definition. The possibility that FDA may act pursuant to the Sugar Association's petition underscores the need for USDA to act quickly to codify a workable definition.

¹⁹ Letter from Stephen Gardner, Director of Litigation, Center for Science in the Public Interest to Docket Management Branch, Food and Drug Administration (Mar. 13, 2006), available at, http://www.cspinet.org/new/pdf/fda_natural.pdf#search=%22natural%22.

²⁰ National Consumers League, *Naturally Misleading: Consumers' Understanding of "Natural" and "Plant-Derived" Labeling Claims*, available at <http://nclnet.org/naturalsreport.pdf> [hereinafter "Naturally Misleading"].

²¹ Letter from Michael F. Jacobson, Ph.D., Executive Director to Christine Lewis Taylor, Ph.D., Director of Office of Nutritional Products, Food and Drug Administration (July 30, 2002) available at www.cspinet.org/new/pdf/bj_complaint.pdf; see also Stop Labeling Lies, Ben & Jerry's Fudging the Truth, Says CSPI, available at, <http://www.stoplabelinglies.com/complaints/benandjerry.html>.

Americas Beverages and Dr. Pepper / Seven UP, Inc. (collectively "Cadbury") engaged in unfair and deceptive acts. In a letter to Cadbury executives, CSPI stated its intention to file a lawsuit over Cadbury's marketing of 7Up as "natural" despite the presence, in the beverage, of high fructose corn syrup, which is not considered minimally processed.²²

b) The codified definition of "natural" should comport with already-established consumer beliefs regarding "natural" foods.

The proposed codified rule should comport with the consumer's current understanding of "natural." As part of its petition, the Sugar Association commissioned a consumer survey. That survey concluded 83% of respondents thought the agencies should implement rules governing "natural" label claims. When asked what "natural" meant to them, 85% of those surveyed said they would not consider any food containing an artificial or a synthetic ingredient to be natural. Regarding processing, 52% thought the amount of processing and 60% agreed altering of raw materials should disqualify a food from a natural claim.²³

Other qualitative consumer research indicates the consumer believes the concept of "natural" applies to substances that can be found in nature or are obtained from renewable sources and are not chemically synthesized or modified.²⁴ The term indicates the absence of artificial colors, artificial fragrances, preservatives and synthetic functional ingredients.²⁵ Quantitative results indicate that 75% of consumers believe natural products are made without chemical additives.²⁶

B. The New Exceptions Added to the Current Natural Policy Create Internal Inconsistencies in the Definition and Render the National Claim Meaningless.

Consumers want a "Natural" label they can trust. They believe it means the product that bears the label contains no artificial ingredients or preservatives and is

²² Letter from Stephen Gardner, Director of Litigation, to Gilbert M. Cassagne and Todd Stitzer (May 10, 2006, available at www.cspinet.org/new/pdf/cadbury_notice.pdf).

²³ Sugar Association Petition, *supra* note 16 at 9.

²⁴ Lambros Kromidas, Making Natural Claims for Personal Care Products: There are no Regulatory Guidelines but the Industry should Put Aside their Varying Interests and Consider what Consumers Expect from Products that make Various "Natural" claims and Formulate Their Products Accordingly, HOUSEHOLD & PERSONAL PRODUCTS INDUSTRY (Dec. 1, 2004), available at, <http://w3.nexis.com/new/frame.do?tokenKey=rsh-20.184768.22334044863&target=results>. [hereinafter "Making Natural Claims for Personal Care Products"].

²⁵ *Id.* (citing Duber-Smith, D.C. 2002. Natural Ingredients and Cosmeceuticals Collide - First Movers are Seeing Green. Soap & Cosmetics, Oct. 32-33.).

²⁶ Naturally Misleading, *supra* note 20.

accomplished with minimal processing. The new FSIS Natural Policy fails to provide for these consumer needs.

Two of the last three paragraphs in the new Natural Policy contain exceptions for (1) ingredients appearing in the National Organic Policy and (2) corn-derived sodium lactate. These exceptions swallow the rule by allowing the presence of artificial ingredients, synthetics and chemical preservatives in “natural” foods. The initial prohibition and subsequent approval of such ingredients renders the Policy internally inconsistent and impracticable, thereby exacerbating consumer confusion and eroding the meaning of Natural claims.

1. The Reference to the National Organic Policy for Acceptable Ingredients for All Natural Claims is Inconsistent with the initially-stated Prohibition on Artificial or Synthetic Ingredients.

The reference to the National Organic Policy (NOP) for a list of acceptable ingredients allowed for natural claims runs afoul of the directive that “natural” products cannot 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[.]” The NOP allows ingredients that, even though they may be naturally derived, would, within context, be considered “artificial” within the Natural Policy. For example, compare the allowance, in the NOP, for “colors, nonsynthetic sources only”²⁷ with the following language in the new Natural Policy:

The decision to approve or deny the use of a natural claim may be affected by the specific context in which the claim is made. For example, claims indicating that a product is a natural food, e.g., “Natural chili” or “chili - a natural product” would be unacceptable for a product containing beet powder which artificially colors the finished product.

The above-quoted passage would specifically prohibit a Natural claim for chili colored with beet powder. However, the reference to the NOP appearing a mere five lines below this passage would approve it. This internal inconsistency creates confusion and renders the Natural label meaningless.

Similarly, the NOP allows synthetic ingredients,²⁸ which, by reference, the new Natural Policy would now also allow for foods for which a Natural claim is made. This, again, creates an inconsistency within the policy as it would again run afoul of the Policy’s initially-stated prohibition on synthetic ingredients.

²⁷ 7 CFR 205.605 (a).

²⁸ 7 CFR 205.605 (b).

2. The Exemption for Sodium Lactate is Inconsistent with the “No Chemical Preservatives” Directive.

The new Natural Policy now also allows the presence of corn-derived sodium lactate in meat and poultry products which would bear a Natural label. This is inconsistent with the Policy’s initial prohibition on chemical preservatives.

Under both the prior and new Natural policies, an applicant for a Natural claim has to demonstrate that its product does not contain any “chemical preservative (as defined in 21 CFR 101.22).” By definition, under 21 CFR 101.22, a “chemical preservative is “any chemical that, when added to food, tends to prevent or retard deterioration thereof.” The rule specifically exempts the common natural preservatives, “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.”²⁹

Sodium lactate “tends to prevent or retard deterioration” of food products to which it is added – it is a “chemical preservative.” This is explicitly recognized in 9 CFR 424.22, which states that sodium lactate is used “to prohibit microbial growth” on “various meat and poultry products.”

a) Even naturally-derived sodium lactate is a preservative.

Sodium lactate is a preservative regardless of its derivation. A recent print advertisement by Purac, a leading seller of food ingredients, makes this explicit. It advertises “natural” lactic acid and states its benefits as “increase[d] shelf life”, “improved food safety” and “control[ling] pathogens.”³⁰

b) Sodium lactate is a preservative even at very low amounts.

Even when used in amounts much less than the 4.8% levels cited in 9 CFR 424.22, sodium lactate is an antimicrobial. Whereas 9 CFR 424.21 also states that sodium lactate may be used as a flavoring at levels not to exceed 2% of the product formulation, 9 CFR 424.21 and 9 CFR 424.22 are not mutually exclusive. Section 424.22 provides only the upper limit for sodium lactate used as a preservative. It prescribes no lower limit below which sodium lactate is not considered a preservative. Section 424.21 merely provides the upper concentration of sodium lactate used as a flavoring. Nowhere do these rules state – or even imply – that sodium lactate is not a preservative, even when used at a level that would also qualify it as a flavorant in certain products.

²⁹ 21 CFR 101.22.

³⁰ See Exhibit B hereto.

In fact, Purac's Opti.Form® *Listeria* Control Model 2005—the computer model manufacturers use to calculate the antimicrobially effective amount of sodium lactate added to their products—indicates sodium lactate is a preservative even when present at very low levels. The chart below summarizes the Opti.Form model results for differing levels of sodium lactate when added to a cured product.³¹

Weight % added Sodium Lactate	Time to 2 log Increase in <i>Listeria</i> Growth	Difference in Time to 2 log Increase from 0 added Sodium Lactate
0%	31 to 38 days	n/a
0.5%	37 to 46 days	6 to 8 days
1.0%	46 to 58 days	15 to 20 days
1.5%	58 to 74 days	27 to 36 days
2.0%	75 to 97 days	44 to 59 days
2.5%	103 to 134 days	72 to 96 days

As the model demonstrates, even when present at only 1% of the product formulation, sodium lactate inhibits microbial growth and confers a two to three week increase in shelf life. At only 2%—the rate up to which some may argue sodium lactate is present as a flavoring—microbial growth is inhibited sufficient to confer a six to eight week increase in shelf life.

These results are further substantiated by reference to the Oscar Mayer patents, which claim antimicrobial effects—specifically a delay in the growth of *Clostridium botulinum*—at lactate levels as low as 1% of the product formulation.³² “The levels of the lactate salt which delay the toxin formation compared to the control are amounts which are effective for delaying the clostridium botulinum growth. In general these amounts range from about 1 to about 7 percent lactate salt and preferably are in the range from about 1.5% to 3.5% lactate salt.”³³

c) Removal of Lactate Preservatives Need Not Compromise Food Safety.

Contrary to arguments that may arise from manufacturers wishing to market “natural” products containing preservatives, the removal of lactate preservatives from “natural” food products will not compromise food safety. It must be reiterated that “natural” is strictly a voluntary claim. If a manufacturer cannot ensure the safety of its products without the addition of lactate preservatives then it is free to omit the “natural” claim from its labels. Responsible manufacturers would not sacrifice food safety in the interests of a marketing initiative.

³¹ See Exhibit C for actual model results.

³² See Exhibit D for the Oscar Mayer patents, 4,798,729; 4,888,191; 5,017,391.

³³ US Patent Nos. 4,798,729 at lines 20-26; 4,888,191 at lines 16-22; 5,017,391 at lines 18-24.

Use of lactate preservatives is not the only avenue for controlling microbial growth. Common salt, sugars, vinegars, spices, smoking, roasting, freezing, drying and fermenting are all natural methods to preserve food and make it safe for consumption. Further, lethality processes, such as high pressure pasteurization, exist that both help to ensure food safety and qualify a product for a "natural" claim.

The real food safety concern surrounding the acceptance of lactates in "natural" products arises from the reduction of the amount of lactate used down to less than 2% of the formulation to meet some arbitrary flavoring limitation.³⁴ Whereas lactates are preservatives³⁵ at very low concentrations, their effectiveness from a food safety standpoint is extremely concentration and temperature dependent. As lactate concentration goes down, so does its effectiveness as a growth inhibitor.³⁶ Similarly, as storage temperature rises above 40°F., the effectiveness of the lactate as a growth inhibitor is reduced.³⁷ The reduction of sodium and potassium lactate concentrations to levels at which they qualify as flavorings to obtain clearance of a "natural" claim compromises food safety by limiting lactate to concentrations which may be ineffective to ensure food safety, especially when combined with less-than-optimal storage temperatures.

IV. Rulemaking is Necessary to Abate the Inconsistencies in the Current Policy, Provide for Customer Confidence and Prevent Erosion of the Natural Claim.

As demonstrated above, the agencies and consumers alike have long recognized and called for a clear, codified definition of "natural" for food labeling purposes. Consumers are confused and mistrustful. If FSIS is to provide for the consumer interest and prevent misleading labeling and the associated erosion of the "natural" claim, it must codify a clear and consistent definition of "natural" that comports with consumers' already-established beliefs. And it must do so in time to prevent FDA from adopting an inconsistent Policy based on the FSIS new Natural Policy, as is called for in the February 28, 2006 Sugar Association petition.³⁸

³⁴ See 9 C.F.R. § 424.21(c).

³⁵ 21 C.F.R. 101.22(a)(5).

³⁶ Food Safety and Inspection Service, Assessing the Effectiveness of the "*Listeria monocytogenes*" Interim Final Rule (Sept. 2004) at 26.

³⁷ R.K. Barakat & L.J. Harris, Growth of *Listeria monocytogenes* and *Yersinia enterocolitica* on Cooked Modified-Atmosphere-Packaged Poultry in the Presence and Absence of a Naturally Occurring Microbiota, APPLIED AND ENVIRONMENTAL MICROBIOLOGY 65:1 (Jan. 1999) 342-45; see Hans Blom, Eva Nerbrink, Richard Dainty, Therese Gagtvedt, Elisabeth Borch, Hilde Nissen, Truls Nesbakken, Addition of 2.5% Lactate and 0.25% Acetate Controls Growth of *Listeria monocytogenes* in Vacuum-Packed, Sensory Acceptable Savelat Sausage and Cooked Ham Stored at 4°C, INT'L J. OF FOOD MICROBIOLOGY 38 (1997) 71-76.

³⁸ See *supra* notes 16-18 and accompanying discussion.

A. Proposed Action

1. Amend 9 CFR 317.8 and 381.129 to codify the original definition of "natural."

As demonstrated above, the reference to the National Organic Policy for a list of allowable ingredients for meat and poultry products bearing natural label claims is internally inconsistent. It both prohibits and allows the presence of artificial flavorings, artificial colorings, and other artificial or synthetic ingredients. Further, the allowance of the presence of corn-derived sodium lactate in meat and poultry products bearing natural label claims also creates internal inconsistency as chemical preservatives are initially prohibited by the Policy.

To alleviate these inconsistencies and abate the potential for consumer confusion and erosion of the meaning of the Natural claim, Hormel Foods Corporation hereby petitions FSIS to codify language in 9 CFR part 317.8 and 381.129 pertaining specifically to Natural Labeling Claims for meat and poultry products. The new rule should codify the definition of "natural" and clarify the circumstances under which it may be used on the label of a meat or poultry product.

It is important to retain a Natural Label policy that does not allow for the use of ingredients that are more than minimally processed and that are not, by themselves, considered to be natural. This is in keeping with the spirit of the reference to "All", "Pure", and "100%" found in the Food Standards and Labeling Policy Book. Accordingly, the new Natural Label Claims Rule should include the following provisions:

Labeling Claims: "Natural, All, 100%"

Conditions of use: The term –"natural, all, 100%" may be used on labeling for meat products and poultry products, provided the applicant for such labeling demonstrates that:

- (1) the product does not contain any artificial flavor or flavoring, artificial 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.

Beyond 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.

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 which do not fundamentally alter the raw product and/or which 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 be considered more than minimal processing. Thus, the use of a natural flavor, flavoring or flavoring agents in compliance with 21 CFR 101.22, 9 CFR 317.2, 381.118 and 424.21 which have undergone more than minimal processing would not be used in products that carry an all natural claim.

Category exceptions: An "all natural" claim will not be invalidated by use of otherwise natural ingredients which contain unavoidable incidental additives or processing aids (as defined in 21 CFR 101.100(a)(3) which may not themselves be considered as natural. Processing aids, such as anticaking or antifoaming agents, have functions in foods that are considered to be physical rather than chemical. Their presence in the final product is insignificant and they have no functional effect in the finished food. Examples include, but are not limited to, calcium silicate, magnesium oxide, calcium carbonate, dimethylpolysiloxane and sodium aluminosilicate.

Labeling requirements: An "all natural" claim may be used in the product name as long as it does not interfere with or alter a standardized name (i.e., All Natural Chili with Beans). An "all natural" claim may also be used as an informative label element either as a standalone feature or to describe some specific aspect of the product (e.g., All Natural Ingredients). The use of the term "all" in conjunction with "natural" must mean that the product as a

whole is natural as stated above with no exceptions other than those stated.

All products claiming to be natural or a natural food should be accompanied by a brief statement which explains what is meant by the term natural, i.e., that the product is a natural food because it contains no preservatives, no artificial flavorings or colorings and is only minimally processed. This statement should appear directly beneath or beside all natural claims or, if elsewhere on the principal display panel, an asterisk should be used to tie the explanation to the claim.

Although some consumers or animal raisers may confuse natural products with those that are free of antibiotics or growth stimulants, this proposed action is not intended to address animal raising. Such claims and the verification of such practices, although acceptable in the use of natural claims, will remain independent and outside the scope of this proposal. (ref: FSIS Natural and Organic Claims <http://www.fsis.usda.gov/OPPDE/larc/Claims/OrganicClaims.htm>)

2. Issue Interim Guidance

The rulemaking process can take one or more years from inception of a petition to promulgation of a final rule. Because consumer confidence and protection of the consumer from being misled is paramount in this instance, the USDA must issue interim guidance. This can be easily and immediately accomplished by issuing a unilateral revision to the current Natural Policy in the same way the August 2005 change to the Policy was issued.

Leaving the new Natural Policy in place during this period will leave the agency and consumers vulnerable to manufacturers attempting to take advantage of its inconsistencies to obtain "natural" labeling for products that contain artificial ingredients or preservatives or that are highly processed. To avoid misleading advertising and further erosion of consumer confidence, the USDA should issue guidance reaffirming the original and continuing two-part "natural" definition that requires the absence of artificial flavors or flavorings, artificial coloring ingredients, chemical preservatives and other artificial or synthetic ingredients and requires minimal processing.

Further, the rescission of the wholesale exemptions for sodium lactate preservatives and ingredients appearing on the National Organic Policy will avoid adverse economic impacts to manufacturers that use the exemptions to gain a market niche, only to have their “natural” status revoked when a new rule is promulgated. It will also protect the investment of those manufacturers that have committed money, time and human resources to development and commercialization of true natural ingredients and minimal processing technologies to produce safe and wholesome products.

V. Environmental Impact

Neither an environmental assessment nor an environmental impact statement is required.

VI. Economic Impact

It is clear that consumers are interested in minimally-processed products that do not contain artificial ingredients or preservatives. But confusion and difficulty in conveniently finding such items are barriers to purchasing. A clear, concise definition will benefit consumers by giving them confidence that the “natural” label really means what they expect it to mean, thereby giving them the confidence to purchase such products. Strong consumer interest, in turn, will encourage retailers to devote more shelf space and marketing attention to these products – and further educate the consumer. Finally, increased consumer and retailer demand for natural products will give incentives to manufacturers to invest in natural ingredients and in new minimal processing technologies. These activities in the consumer, manufacturer and retailer ranks will result in wide-ranging positive economic impacts.

A. Increased Consumer Confidence in the Natural Label will have a Positive Economic Impact.

1. Protection of the integrity of the Natural label will ensure the continued growth and viability of the natural category.

“Health and wellness is no longer a niche – it’s mainstream and it’s a long-term trend.”³⁹ All reports are that consumers want to eat healthy.⁴⁰ 70% of shoppers feel their diets could be a lot or somewhat healthier and 51% are making significant efforts to eat healthy. 52% look at the nutrition label when they buy an item for the first time. 26% of consumers have purchased a food item because of information on a food

³⁹ Maryellen Molyneux, Putting Words into Action; Services of the Natural Marketing Institute, SUPERMARKET NEWS (Feb. 28, 2005) [hereinafter “Putting Words into Action”].

⁴⁰ See, e.g., FMI News Release, U.S. Families Taking Charge of Health, But Convenience is Key Driver in Food-Purchasing Decisions, According to New FMI/PREVENTION Study (Aug. 18, 2003), available at, <http://fmi.org/media/mediatext.cfm?id=565>.

nutrition label and 34% have rejected an item because of nutrition label information or a lack thereof.⁴¹ In 2002, 67% of shoppers checked food labels to determine the type of preservative present in their food – an 8% increase over 2001.⁴²

These diet concerns are raising consumer interest in, and demand for, natural and organic products. “All-natural” is the most frequent positive new product category in North America. FoodTechnology magazine reports that traditional recipes are making a comeback as natural ingredients and ideas are becoming paramount.⁴³ According to a nationwide survey by HealthFocus, “[m]ore consumers are eating natural foods than ever before as a way of adapting lifestyles with moderation and balance as key elements[.]”⁴⁴ As of 2001, almost 75% of the general population reported using natural foods, with a large group reporting their first use of natural and organic products in 2000.⁴⁵

The consumer trend toward natural and organic products is evidenced by the growing number of businesses catering to consumers wishing to purchase natural food products. Food sales in natural product stores reached a reported \$11.4 billion in 2003.⁴⁶ Natural product sales in all channels reached \$42.8 billion in 2003, an 8.1% increase from 2002. Natural product retailers saw sales of \$20.5 billion, reflecting a 9.9% increase from 2002.⁴⁷ According to Supermarket News:

“Today’s consumers are increasingly concerned with food safety and the question of ‘where does my food come from?’ . . . They are seeking natural products – natural product sales have topped \$34 billion in recent years and are growing – and the advancing age of baby boomers is helping to drive the category. Consumers will pay 50 to 60 cents more for premium organic or natural meat because the perceived health benefits outweigh costs in many consumers’ minds.”⁴⁸

⁴¹ FMI News Release, U.S. Consumers Buying Fortified Foods, Organic Produce and Prescription Drugs at Nation’s Supermarkets, According to Shopping for Health 2001 (Nov. 19, 2001), available at, <http://fmi.org/media/mediatext.cfm?13=371> [hereinafter “U.S. Consumers Buying Fortified Foods”].

⁴² *Supra* note at 14.

⁴³ A. Elizabeth Sloan, New Product Showcases Sizzle, *supra* note 15 at 40.

⁴⁴ Study Finds More Americans Eating Natural Foods, NATURAL FOODS MERCHANDISER (May 1997).

⁴⁵ Steve French, Statshot of Consumer Trends: Natural Products Channel is no Longer Niche Market as Increasing Number of Consumers are Using These Markets, NATURAL FOODS MERCHANDISER (June 2001) [hereinafter “Statshot of Consumer Trends”].

⁴⁶ Sugar Association Petition, *supra* note 16 at 4.

⁴⁷ A. Elizabeth Sloan, Gourmet & Specialty Food Trends, FoodTechnology 26-38, 28 (July 2004) [hereinafter “Gourmet & Specialty Food Trends”].

⁴⁸ Bobbie Katz, Organic, Natural Meat Sales are Exploding (Feb 28, 2005) (quoting Nicholas D’Agostino III, vice president, D’Agostino Supermarkets, New York).

The demographics of those who generally buy organic foods cut across all generations:

<u>Demographic</u>	<u>Regularly Buying Organics</u>
Generation Y (18-27)	51%
Generation X (28-41)	55%
Younger Baby Boomers (42-51)	57%
Older Baby Boomers (52-60)	50%
Matures (61+)	46%

Interest in organic products correlates strongly with childcare giving. 32% of buyers reported their first purchase of organic foods was for an infant or newborn.⁴⁹

The natural channel will only continue to grow. According to NMI, in 2004, 63% of consumers use natural foods and beverages and 40% use organics; 53% want foods grown without pesticides; 49% want natural foods; and 18% use only natural sugars such as honey and raw sugar. Issues of increasing importance are foods free of antibiotics, hormones and preservatives.⁵⁰ This mainstreaming of natural foods has drawn major manufacturers into the market.⁵¹

Mainstreaming has extended to retailers as well. Once available only in natural foods and nutrition stores, natural foods are now a growing category with mainstream retailers. Research shows consumers prefer to see all their options in one location⁵² and that they are more likely to try a natural or organic counterpart under those circumstances.⁵³ Mainstream retailers, recognizing the trend toward a preference for natural and organic foods, have begun developing specific strategies for offering them in their stores.⁵⁴ Many retailers are addressing consumer confusion regarding natural and organic products by providing specific informational services. Services include in-store advertising, cooking demonstrations, and employing resident specialists to answer questions.⁵⁵ Providing conventional counterpart items and running price

⁴⁹ FMI Backgrounder Natural and Organic Foods, 3 available at, http://www.fmi.org/media/bg/natural_organic_foods.pdf [hereinafter "FMI Backgrounder"], 5.

⁵⁰ Gourmet & Specialty Food Trends, *supra* note 47 at 31.

⁵¹ FMI Backgrounder *supra* note 49.

⁵² Putting Words into Action, *supra* note 39.

⁵³ FMI Backgrounder, *supra* note 49 at 6.

⁵⁴ FMI Backgrounder, *supra* note 49; Statshot of Consumer Trends, *supra* note at 45.

⁵⁵ FMI Backgrounder, *supra* note 49 at 6; Food Marketing Institute Release, Convenience, Cost and Nutrition are Key Concerns in Health & Self-Care Movement, According to "Shopping for Health 2003" (Nov. 4, 2003), available at, <http://fmi.org/media/mediatext.cfm?id=578> ["hereinafter Convenience, Cost and Nutrition"] ("These barriers are areas of opportunity for supermarkets to help consumers manage their health by providing valuable nutrition information and convenient, healthy meal options.").

promotions round out retailer marketing strategies for these products.⁵⁶

Increased availability of natural and organic products in mainstream channels makes these products visible to a wider range of consumers, many of which would not have otherwise been introduced to such products in a natural foods or nutrition store. This, in turn, brings a new consumer base to manufacturers offering such products. In fact, increased mainstream availability of natural and organic products is driving new consumers into natural products stores.⁵⁷

Consumers blame their lack of success in efforts to eat healthy, in part, on the high costs of healthy foods.⁵⁸ Price premiums for organics range around 35-53% for baby food, 72% for frozen broccoli, 94% for spring wheat and 177% for soybeans.⁵⁹ However, as major manufacturers begin offering such products, mass production will lead to price competition with conventional products and reduce prices for the consumer.⁶⁰

2. Protection of the integrity of the Natural label will open the category to consumers with special health needs.

Consumers also cite health benefits as their motivation to purchase natural and organic foods.⁶¹ Natural foods consumers are statistically more likely to have philosophical or health-related special dietary needs.⁶² Approximately five million Americans—2% of adults and 2-8% of children—suffer from some type of food allergy.⁶³ More common, however, than food allergies are food intolerances. Food intolerance, unlike a food allergy, does not involve the immune system, but instead is a reaction to the chemical composition of the food, such as a preservative or flavoring.⁶⁴

Food allergies and intolerance are related to a wide range of physical reactions, including respiratory problems, rashes and headaches.⁶⁵ More disconcerting are the

⁵⁶ FMI Backgrounder, *supra* note 49.

⁵⁷ Statshot of Consumer Trends, *supra* note 45.

⁵⁸ U.S. Consumers Buying Fortified Foods, *supra* note 41.

⁵⁹ FMI Backgrounder, *supra* note 49 at 6.

⁶⁰ *Id.* at 6.

⁶¹ *Id.* at 3.

⁶² Josh Dinar, Food for Thought: Why they Buy, NATURAL FOODS MERCHANDISER (Dec. 2000) [hereinafter "Food for Thought"].

⁶³ Citizen Petition by the Attorneys General of NY, MD, MI, WY, OH, TN CT, VT, and MA to requesting action by the Food and Drug Administration regarding allergenic substances, *available at*, http://www.oag.state.ny.us/press/2000/may/may26a_attach_00.html.

⁶⁴ 71 FR 26677-03, 26678.

⁶⁵ See Food Additives, Australian Consumers' Association, Choice (April 2005), *available at*, <http://www.choice.com.au/viewarticleonpage.aspx?id=100241&catId=100545&tid=100008&p=1> [hereinafter "Food Additives"]; Food Issues, *available at*, <http://www.understandingfoodadditives.org/pages/Ch5p2-1.htm>.

studies that link food additives with behavioral problems, hyperactivity and brain processing in children.⁶⁶ In the 1970's, Dr. Ben Feingold, in *Why Your Child is Hyperactive*, published results claiming a diet free of synthetic colorings, preservatives and salicylates improved behavior in 30-50% of hyperactive children.⁶⁷ Sodium lactate, one of the preservatives the new Natural Policy specifically allows, is linked to adverse reactions in lactose intolerant children.⁶⁸

As the FSIS has already recognized, food allergic and intolerant consumers and their caregivers are entitled to accurate information and confidence that "all ingredients will be correctly labeled on products."⁶⁹ These consumers want to have confidence that their choices are real.⁷⁰ A clear, concise, exception-free definition of "natural" will give them the assurances they need to make health-conscious purchases for themselves and their children.

3. Protection of the integrity of the Natural label may help to open international markets.

Finally, a clear, enforceable definition of "natural" has the potential to open foreign markets. There is strong growth in the natural category in Latin America.⁷¹ Without reliable parameters governing the use of the term, the global market remains uncertain. The implementation, by U.S. regulators, of a clear and enforceable definition of "natural" will assist in establishing equivalency of regulation under various free trade agreements and establish trust in product labeling that could potentially open foreign markets.⁷²

⁶⁶ See Food Additives, *supra* note 65; Food Issues, *supra* note 65; Natural Health and Longevity Resource Center, Food Additives and Hyperactivity in Children, available at, <http://www.all-natural.com/hyperactivity.htm>; BBC News, Food Additives "Cause Tantrums" (Oct. 25, 2002), available at, <http://news.bbc.co.uk/1/hi/health/2356163.stm>.

⁶⁷ Food Issues, *supra* note 65.

⁶⁸ Food Additives: Acids, Antioxidants, Mineral Salts, available at, <http://www.lactose.co.uk/milkallergy/foodadditives300.html>.

⁶⁹ 71 FR 26677, 26678.

⁷⁰ Food for Thought, *supra* note 62.

⁷¹ A. Elizabeth Sloan, New Product Showcases Sizzle, *supra* note 15 at 40.

⁷² See PanAfrica; When Ethics Mean Business, AFRICA NEWS (Mar. 15, 2005).

B. A Clear Definition and Use Parameters Governing the Use of Natural Label Claims Will Also Positively Impact Manufacturers.

Beyond the generation of more sales generally due to increased consumer confidence and trust, a codified definition of “natural” including parameters for making such a claim will benefit manufacturers by providing assurance that the term is consistently used, thereby leveling the playing field among competitors. Further, a definition that eliminates exceptions that encourage reductions in amounts of certain food safety-enhancing ingredients to an arbitrary level will protect the category, and its players, from a potentially devastating food safety incident.⁷³

A clear definition will encourage investment in innovation, especially in new minimal processing technologies, and investment in natural, sustainable ingredient supplies. And it will protect these investments from other manufacturers that would take advantage of the exceptions to use less expensive substitutes for minimal processing techniques and chemical and artificial ingredients and preservatives.

Finally, it must be remembered that “natural” is strictly a voluntary claim. Any negative impact to manufacturers which may have obtained approval of a natural label through use of the exceptions in the new Policy has chosen to exploit the Policy and consumer confidence in this manner to make this voluntary claim. This perceived negative impact is better borne by the manufacturer than by the consumer however, and can be expeditious action by the FSIS in issuing interim guidance and moving through the rulemaking process.

VI. Conclusion

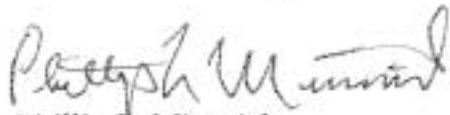
It is clear that natural products are important to consumers. It is equally clear that consumers are confused about the definition of “natural” and, consequently, are becoming distrustful of the labeling claims. The agencies, consumers and manufacturers have long been aware of these problems and have called for rulemaking. Now is the time for USDA-FSIS to codify a clear, concise definition of “natural” that furthers the consumer interests and reflects the consumer’s concepts of the term.

⁷³ See *supra* discussion of food safety issues at p.12.

VII. Certification

The undersigned certifies that, to the best of their knowledge, this petition includes all information and views on which the petition relies and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

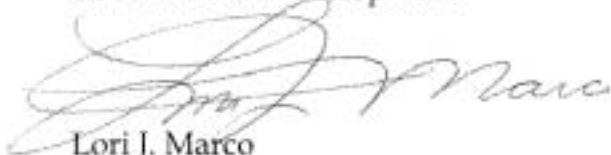
Respectfully submitted,
Hormel Foods Corporation



Phillip L. Minerich
Vice President Research & Development



Mark S. Roberts
Manager, Technical Services and Regulatory Affairs
Research and Development



Lori J. Marco
Corporate Attorney

cc: The Honorable Richard Raymond, Under Secretary of Food Safety
U.S. Department of Agriculture