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Gerrit Vreeman

FSIS Docket Room
Docket Clerk
U.S. Department of Agriculture
Food Safety and Inspection Service
300 12th Street SW, Room 102 Cotton Annex
Washington, DC 20250

RE: **Comments from Purac America, Inc. to FSIS Regarding the Definition of "Natural"; Docket No. FSIS 2006-0040**

Dear Sir or Madam:

PURAC appreciates the opportunity to submit comments to the Food Safety and Inspection Service (FSIS) regarding the definition and use of the term "natural" to describe meat and poultry products on food labels. As a supplier of lactate ingredients for numerous meat and poultry products, PURAC is greatly concerned with any suggestion that sodium lactate from corn is incompatible with a "natural" claim. FSIS has allowed and should continue to permit the use of sodium lactate in "natural" products. Sodium lactate is not a chemical preservative and is derived by no more than minimal processing from a natural, renewable source. There is no legal or factual basis to exclude sodium lactate and other ingredients that enhance the safety and quality of numerous "natural" meat and poultry products.

PURAC America is the U.S. subsidiary of PURAC, headquartered in Holland, and has been providing sales and expert technical support to customers in this country since 1983. PURAC is the world's largest producer of natural lactic acid, lactates, gluconates, lactitol, lactides and polylactides. PURAC is a subsidiary of CSM, a global leader engaged in the development, production, sale and distribution of bakery supplies and food ingredients. We are proud of the role it has played working with numerous meat and poultry processor in the U.S. to pioneer, refine and achieve practical applications for sodium lactate as a valuable food safety tool resulting in a safer food supply for the nation.

PURAC America is part of the PURAC division, Manufacturer of *natural* lactic acid, lactates and gluconates.

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SUMMARY OF COMMENT

PURAC views the recent actions of the agency, reflected in its December 5, 2006 *Federal Register* Notice (the Notice), 1/ as premature and ill-considered. The FSIS's long-standing "natural" policy, developed in 1982 and updated over the years, has never served as a bar to the use of sodium lactate and other natural preservatives, nor should it. We have carefully reviewed the Hormel Petition (the Petition) 2/ referenced in the Notice and respectfully find that it fails to provide a sufficient basis for the requested action. PURAC also is deeply troubled by the procedural approach FSIS has adopted.

This comment sets forth the following.

- Sodium lactate derived from corn via fermentation complies fully with the longstanding "natural" regulatory policy in that it is neither a chemical preservative nor a synthetic ingredient and it is not more than minimally processed. 3/

- Sodium lactate from corn is not a chemical preservative. Similar to common salt, sugars, vinegars, spices, and wood smoke, sodium lactate is a natural preservative used predominantly to control pathogen growth and offers food processors a valuable tool to address a range of other technical effects.

- There is no legal or scientific basis for preventing sodium lactate or other antimicrobial or preservative ingredients in foods characterized as "natural." Preservatives that are themselves natural should be continued to be used in "natural" products.

- Barring sodium lactate and other natural preservatives lessens the food safety tools vital to the development of safe, wholesome "natural" products. FSIS should resist regulatory policies that contract rather than expand the food safety tools available to processors.

- In order to encompass or allow for the varied, appropriate meanings "natural" conveys to consumers, a flexible policy allowing for the case-by-case

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1/ "Product Labeling: Definition of the Term 'Natural,'" 71 Fed. Reg. 70503 (Dec. 5, 2006).

2/ Hormel Foods Corp., "Petition for the Issuance of a Rule Regarding Natural Label Claims" (Oct. 9, 2006, revised Oct. 25, 2006) available at: http://www.fsis.usda.gov/Regulations_&_Policies/Petition_Natural_Label_Claims/index.asp.

3/ Throughout this document, any reference to "sodium lactate" or lactates generally should be considered to include potassium lactate. Also, any reference to "sodium lactate (from corn)" is intended to encompass lactates derived from any natural, renewable resource (*e.g.*, corn, beets, sugar cane).

assessment of the term now in place should continue. The appropriateness of a claim will necessarily depend on the food, product category, and context. These considerations cannot be captured in a static regulation that over time will surely become outdated and prove unduly restrictive.

- Finally, the process followed by the agency in response to the Petition raises distinct concerns. Overall, neither consumers nor industry would be well served by an attempt at rulemaking that we believe is ill-suited to ensuring that "natural" claims inform and not mislead consumers. Rather, FSIS should resume its context-specific evaluation of "natural" claims through the prior label approval system.

I. SODIUM LACTATE IN MEAT AND POULTRY PRODUCTS IS CONSISTENT WITH A "NATURAL" CLAIM

The FSIS "natural" policy authorizes a "natural" claim if: (1) the product does not contain any artificial flavor or flavoring, coloring ingredient, or chemical preservative or any other artificial or synthetic ingredient; and (2) the product and its ingredients are not more than minimally processed. 4/ Sodium lactate satisfies this policy and has been used in numerous FSIS-regulated products for which label approvals have been granted.

A. Sodium Lactate is Neither a Synthetic Nor an Artificial Ingredient and it is Not a Chemical Preservative

1. Sodium lactate is a natural ingredient comparable to many other ingredients commonly found in "natural" products

Synthetic or artificial ingredients are often easily distinguished based on the materials from which they are derived. Sodium lactate is the sodium salt of lactic acid, an organic acid. Through a proprietary manufacturing process, PURAC's sodium lactate is derived from corn sugar via fermentation. The process is designed to yield the L form of lactate, which is identical to lactate naturally present in foods and in the human body. Corn sugar is fermented by bacteria to obtain lactic acid, which is then filtered, evaporated, and purified. (As previously noted, corn is one of several renewable source materials that can be used to produce sodium lactate; sugar beet and sugar cane are others.) The lactic acid is then neutralized to form sodium or potassium lactate for use in meat products.

In contrast to synthetic, artificial and chemical preservatives, lactates are naturally present in our body and the foods we eat. Lactate is a natural constituent of all active skeletal muscle tissues, resulting from the anaerobic glycolysis, or metabolism, of glucose. In the Krebs cycle, which generates energy for active tissues using oxygen, the end products of glycolysis – pyruvate and L lactate – are further metabolized to carbon dioxide and water. Under limited oxygen conditions, pyruvate is converted to L lactate in order to regenerate certain cellular chemicals that are needed for the citric acid to continue to produce energy. 5/ L lactates and/or L lactic acid are, therefore, natural constituents of human muscle

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4/ U.S. Department of Agriculture, Food Safety and Inspection Service, "Natural Claims" in *Food Standards and Labeling Policy Book* (Nov. 2006).

5/ Lactate is essentially a" metabolite, which must be converted back to pyruvate before it can be further metabolized, and all tissues have significant levels of the enzyme lactate dehydrogenase to facilitate the conversion. Most muscles, including animal muscles used as food, contain a certain low level of lactate in the living tissue. *See* L. Stryer, *Biochemistry* (2nd ed., W.H.. Freeman and Co. 1981).

tissue, with elevated levels present after strenuous exercise. 6/ A substance found in, and produced by, humans and animals conveys the natural status of PURAC's sodium lactate.

Consumers also regularly encounter lactate naturally occurring in many commonly consumed muscle foods. In the biological conversion of muscle to meat, muscles cells continue post mortem metabolism of glycogen to produce glucose and then produce L lactic acid via glycolysis, as mentioned above. 7/ Measurements of lactic acid in meat have been reported in numerous meat science publications, and the lactate concentrations naturally present in various foods include pork (1-1.2%, expressed as sodium lactate), salmon (0.6% expressed as lactic acid or 0.8-0.9% expressed as sodium lactate), hamburger (0.7% expressed as lactic acid), sausage (0.8% expressed as sodium lactate), bacon (0.6% expressed as sodium lactate), and frankfurters (0.8% expressed as sodium lactate). 8/ Sodium lactate, whether naturally occurring or added, is not synthetic or foreign to our bodies and the many foods we eat.

The natural status of sodium lactate is reinforced by its similarity to other food ingredients commonly viewed as natural.

- Common food grade salt undergoes significant purification to remove other mineral impurities. This can involve chemical treatment to facilitate precipitation of minerals such as calcium, magnesium and others. Anti-caking agents, such as tricalcium phosphate, calcium or magnesium carbonates, fatty acid salts (acid salts), magnesium oxide, silicon dioxide, sodium alumino-silicate, and alumino-calcium silicate, are added.

6/ *See* N. McCartney *et al.*, "Muscle power and metabolism in maximal intermittent exercise," *J. Appl. Physiol.* 60: 1164-9 (1986); H. Rothstein, *General Physiology: The Cellular Molecular Basis* 516 (Ginn and Co. 1971).

7/ The level of glycogen in muscle of a food animal will vary depending on nutritional status of the animal prior to slaughter. It can be as high as 1% of the weight of the tissue and essentially will be completely converted to lactic acid. Post mortem glycolysis that produces lactic acid results in the decrease in pH of muscle from the initial physiological value of 7.4. The pH of meat usually ranges from to 5.4 to 6.4 and more commonly is 5.8 to 6.0, reflecting the L lactic acid that is produced from post mortem glycolysis. The muscle then buffers this to a higher pH and the lactic acid is converted to a neutral salt, such as calcium, potassium or sodium lactate.

8/ Unpublished sampling data conducted by PURAC (2002-2006). *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).

- Sugar is refined from sugar cane and sugar beets. They are crushed to release a sucrose-rich liquor that is refined through further processing. The crude liquor has large amounts of impurities including cellulosic fiber and soil particles. The crude liquor can be treated with lime and phosphoric acid to remove impurities before evaporation by boiling and/or with vacuum evaporation to ultimately crystallize the sugar. Decolorization methods use granular activated carbon, powdered activated carbon, ion exchange resins, and other materials.

- Vinegar is made from the oxidation of ethanol into acetic acid. The ethanol source can be wine, cider, beer, fermented fruit juice, or nearly any other liquid containing alcohol. Commercial vinegar is produced by fermentation using specific organisms, specifically yeast and *Acetobactor*, to first generate alcohol from a sugar source (*e.g.*, a grain, such as corn) and then to convert the alcohol into acetic acid.

- Spices are derived from plant materials, derived from various levels of processing and refining from their original source. Although these ingredients possess useful antimicrobial properties, this class of ingredients are not considered chemical preservatives, synthetic, or artificial ingredients.

Each of these examples illustrate the processing of a food ingredient starting with natural, renewable raw materials. These processing and treatment steps have not been viewed by FSIS as evidence that these ingredients are in some fashion synthetic, artificial, or chemical preservatives or more than minimally processed. There is no scientific or factual basis to single-out sodium lactate from these and other comparable natural ingredients.

Regulatory classification of natural and artificial flavors further reinforces the natural status of sodium lactate. FSIS define "natural flavor" as:

> The term "natural flavor," "natural flavoring," "flavor," or "flavoring" means the essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate, or any other product of 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. 9/

In the context of flavors, FSIS has identified the type of materials and processing steps consistent with use of the term "natural". Starting from various raw materials, a natural flavor can be derived by employing extraction, enzymolysis and fermentation, among other processes. FDA devised a similar definition of a "natural" flavor, which allows for comparable flexibility. 10/

The distinction drawn by the agencies between "natural" and "artificial" ingredients is apparent and instructive. The source of the ingredient – the raw material from which it is derived – is the primary focus for determining its general qualities, attributes, and naming convention. This concept is a useful parallel in understanding how FSIS and FDA have employed their respective "natural" policies to ensure that such claims are used in a truthful, non-misleading fashion.

2. Synthetic, artificial ingredients are readily identifiable and properly excluded from use in "natural" foods

FSIS readily distinguishes synthetic, artificial ingredients from naturally-sourced ingredients in applying its "natural" policy. There are broad categories of safe and suitable food ingredients that are not natural. We offer a few examples of chemical preservatives that illustrate the marked contrast to sodium lactate and other natural ingredients.

Butylated hydroxyanisole (BHA) is an antioxidant that is a mixture of two isomeric organic compounds, (2-*tert*-butyl-4-hydroxyanisole and 3-*tert*-butyl-4-hydroxyanisole) prepared from petrochemical-derived 4-methoxyphenol and isobutylene. Another antioxidant, butylated hydroxytoluene (BHT), is also produced from petrochemicals either by the alkylation of p-cresol with isobutylene or by the dibutylation of m,p-cresol mixtures and separation of the resulting butylates, both notably synthetic processes. A third antioxidant, *tert*-butylhydroquinone (TBHQ), is also synthetically-derived from petrochemicals.

In contrast to PURAC's naturally-sourced sodium lactate, there are synthetic forms of sodium lactate. The starting raw materials for synthetic lactic

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9/ 9 CFR § 317.2(f)(1)(i)(B). Note that FSIS has advised that commonly used acids (*e.g.*, ascorbic, citric, lactic, etc.) must be designated by their specific name and not by a collective term (*e.g.*, "flavors). This guidance pertains, of course, to the appropriate terminology in connection with the naming conventions used in the ingredient statement.

10/ 21 C.F.R. § 101.22(a)(3).

acid are petrochemical in origin. 11/ Artificial flavors represents another class of ingredients that are reasonably understood as derived from non-natural source materials and thus are not permitted in natural products. For example, artificial vanillin is made through a two-step process from the petrochemical precursors guaiacol and glyoxylic acid.

3. Sodium lactate is not a chemical preservative

Until very recently, FSIS categorically deemed sodium lactate (derived from corn) permissible in a "natural" product. The Notice confirms that the express allowance of sodium lactate was a product of the agency's long-standing practice of modifying this guidance "to reflect case-by-case decisions made by the Agency" and to "make it consistent with prevailing policies." 12/ It now appears that FSIS has inexplicably reversed course and views the antimicrobial characteristics of sodium lactate to conflict with the policy. As noted above, FSIS has yet to clearly articulate why sodium lactate is now considered at odds with a "natural" claim.

In apparent response to the Petition, FSIS advised: "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." 13/ Reference is made to information received "that raises questions about when, and if, a food to which sodium lactate has been added would be fairly characterized as natural." 14/ The Petition, addressed below, offers that sodium lactate in a "natural" product "is inconsistent with the Policy's initial prohibition on chemical preservatives." 15/

PURAC is greatly troubled by the apparent acquiescence to the Petitioner's views on sodium lactate. Even before the public hearing was held, FSIS revoked the portion of its "natural" policy that expressly allowed for the use of sodium lactate in "natural" products. Equally disturbing is a decision by FSIS to

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11/ The side-by-side availability of naturally-sourced and synthetically produced sodium lactate is itself instructive. It is our understanding that FSIS, in making case-by-case determinations on "natural" ingredients, evaluates the source and commercial availability of comparable ingredients.

12/ 71 Fed. Reg. at 70504.

13/ *Id.*

14/ *Id.*

15/ Petition at 10. The Petitioner argues that FSIS has adopted the FDA definition for chemical preservative which has long been referenced in the FSIS policy. FDA has defined a "chemical preservative" to include "any chemical that, when added to food, tends to prevent or retard deterioration thereof." The Petition suggests: "sodium lactate 'tends to prevent or retard deterioration' of food products to which it is added – it is a chemical preservative.

revoke existing label approvals for "natural" products containing sodium lactate. It is our understanding that such letters advise firms that if sodium lactate is used for its antimicrobial benefits that the label approval will be revoked. It appears that antimicrobial ingredients and other preservatives are, for the first time, deemed in conflict with a "natural" claim. 16/ It is puzzling how an ingredient is "natural" as a flavor but somehow becomes a synthetic, artificial, chemical preservative if added for its antimicrobial benefits.

The FSIS "natural" policy has not, and should not, be applied in a manner that prohibits the use of sodium lactate (or any other natural preservative) because of its useful antimicrobial/preservative properties. To view all such ingredients as "chemical preservatives" distorts the plain meaning of the "natural" policy and will effectively bar the use of traditional and newer antimicrobial preservative ingredients that otherwise fully comply with the two-prong "natural" policy.

4. The "chemical preservative" exclusion cannot be rationally interpreted to bar all preservatives

On its face, the meaning of "chemical preservative" is so broad as to render the term largely meaningless for setting limits on the use of a "natural" claim. All things found in nature are chemicals. Moreover, a literal application of FDA's definition of "chemical preservative" would bar any ingredient or processing method that "tends to prevent or retard deterioration." 17/ Virtually any form of preservation, dating back thousands of years, would be prohibited from bearing a "natural" claim if FSIS follows this path. A policy that bars sodium lactate and other antimicrobial/preservative ingredients would effectively "read-out" the term "chemical" from the prohibition whereby all preservatives and forms of preservation would disqualify use of the "natural" claim. 18/

The meaning of "chemical preservative" is most appropriately determined in the context of the policy. Of course, "preservative" is tied to and limited by "chemical" such that not all preservatives are precluded from use in

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16/ As discussed later in our comments, we find this position surprising given that the antimicrobial properties of sodium lactate have been well known to the agency and the food industry for years.

17/ "Deterioration" in the food context can relate to a myriad of issues, including microbial growth, spoilage, or lack of pathogen control; loss of appropriate color, flavor or taste profiles; or reduction of nutritional value.

18/ Literally applying the FDA definition of "chemical preservative" arguably takes the term out of context. While it may have seemed reasonable to include this cross-reference in 1982, FSIS must determine what constitutes a "chemical preservative" in a manner that is reasonable and appropriate in the context of a "natural" claim.

"natural" products. Moreover, "chemical preservative" is followed by the phrase "or any other artificial or synthetic ingredient." A chemical preservative barred by the policy are those ingredients that are akin to "other artificial or synthetic" ingredients. The FSIS policy cannot be construed to bar all preservatives.

5. Lactates have a long history of use as a natural food preservative, confirming the appropriateness of its use in natural meat and poultry products

Beyond the regulatory parameters for "chemical preservative," the natural characteristics of sodium lactate are underscored by comparing sodium lactate to many other commonly used ingredients that satisfy the two-prong "natural" policy and exert known antimicrobial and other preservative affects on meat and poultry products.

Lactate salts and lactic acid, as products of fermentation, have been used for food preservation and flavoring purposes for thousands of years. Fermented foods likely were among the first foods consumed by humans because fermentation was inevitable when raw food materials were not consumed prior to the development of substantial microbial growth. For example, when milk was collected, it had to be consumed in a matter of hours or else it would sour and curdle. However, controlled fermentation of milk or fractions could preserve the milk in the form of cheese and yoghurt. It likely was recognized that fermented foods were less perishable and safer to consume than their raw ingredients from which they were made. 19/ The salting of meat, of course, allowed for long sea voyages and provided a form of preservation that enabled Europeans to reach America.

In the 19th century, Pasteur recognized that microorganisms were responsible for the fermentation of milk and other foods. This discovery gave rise to the development of the modern day fermented foods. Lactic acid bacteria are among the most frequently used microorganisms in fermented foods, used for preservation of cheese, milk, yogurt, sausages, pickles, olives, and sauerkraut. Lactic acid can be present at 1-1.5% in these products. 20/ As both a preservative and a flavor, lactic acid also is added to acidified foods, such as pickles, dairy, salads, dressings, and beverages, while lactate salts are used in foods with near neutral pH, such as meat and poultry products.

Modern food fermentations involve formulation of the products with an added sugar as an ingredient and addition of a starter culture inoculum. The material is held under conditions that facilitate growth of the organism during

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19/ R.W. Hutkins, *Microbiology and Technology of Fermented Foods*, (Blackwell Publishing 2006).

20/ B. Ray and M. Daeschel, *Food Biopreservatives of Microbial Origin.* (CRC Press 1992).

which time it anaerobically metabolizes the sugar to support its growth. The products of metabolism include a number of preservative compounds, including organic acids, amino acids, esters, fatty acids, and nucleotides.

The particular acid produced by the fermentation is dominated by the selection of the culture organism but is also significantly influenced by the added sugar and conditions of production. The acid production can have an important influence on the texture of the product by gradually denaturing proteins during the fermentation process. Acetic, lactic, and propionic acids are produced in abundance as by-products of the fermentation and are major characteristics of the products. Acetic acid fermentations are used to produce vinegars and pickles. Lactic acid fermentations are significant for fermented sausages, yoghurt and some pickles. Propionic acid fermentations are important for some cheeses most notably Swiss cheese. Notably, the yeast used in producing bread generates carbon dioxide which provides the leavening activity but also can produce measurable quantities of lactic and acetic acids in sourdough products. Fermented beverages typically employ yeast to produce alcohol.

The capacity of lactic acid bacteria to produce large amounts of lactic acid is one of the factors contributing to their ecological success. Lactic acid and lactates inhibit the growth of non-lactic acid bacteria, specifically the outgrowth of pathogens and spoilage bacteria. The suggested mechanisms of antimicrobial action of lactic acid and lactates include feedback inhibition, intracellular acidulation, interference with proton transfer across cell membranes, and reduced water activity, with the undissociated and dissociated forms contributing a combined effect. 21/ In comparison to salt, both reduce water activity, act to suppress pathogen growth, and serve as flavor enhancers through surface, injection, or emulsion applications. Herbs and spices can have some antioxidant and antimicrobial properties. Such properties have been ascribed to mustard, cinnamon, cloves, hops, rosemary, and garlic.

Prohibiting an ingredient solely because it exerts an antimicrobial or any other preservative effect in the food in which it is incorporated is nonsensical. There are numerous dual- or multi-use ingredients that comply with the fundamental requirements of the "natural" policy and possess preservative properties in addition to other functions (*e.g.*, flavors, nutrients, binders, humectants, stabilizers). For example, few consumers would question the use of salt, vinegar, or rosemary, or citric acid in a "natural" product, yet their preservative properties would appear to be at odds with the policy proposed by the Petitioner. FSIS has further complicated matters by calling-out only the use of sodium lactate as a preservative without questioning the many other ingredients that possess similar characteristics. In PURAC's view, all of these ingredients are

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21/ R.G. Cassens, *Meat Preservation: Preventing Losses and Assuring Safety*, 91 (Food & Nutrition Press, Inc. 1994).

appropriate for use in a "natural" product because they are consistent with the agency's two-prong policy.

B. PURAC's Sodium Lactate is Not More Than Minimally Processed

FSIS has already determined that sodium lactate from corn is not more than minimally processed. In its Notice, letters to individual companies, and in other statements by agency officials there has been no indication that the agency would, for the first time, consider sodium lactate (derived from corn or other agricultural commodity) as more than minimally processed. Indeed, there is no rational basis upon which the agency could support such a finding.

In August 2005, FSIS updated the "natural" policy "by acknowledging that sugar, sodium lactate (from a corn source), and natural flavorings from oleoresins or extractives could be acceptable for products bearing 'natural' claims." 22/ The Notice in turn reflects the agency's new-found concern that sodium lactate is not appropriate for use in "natural" products due to its antimicrobial properties. On an interim basis, the Notice advises of a case-by-case approach where the agency will examine factors "such as the level used, the claimed technical effect of the sodium lactate, and the actual effect that it is having on the product." 23/ The recent agency letters questioning label approvals for "natural" products containing sodium lactate similarly focus on the antimicrobial properties of the ingredient.

PURAC's sodium lactate is not more than minimally processed. The primary processing step of PURAC's sodium lactate is the fermentation of corn sugar to create L lactic acid, which is then filtered, evaporated, and purified. The L lactic acid is then neutralized to form a lactate salt for use in meat products. The fermentation is specifically listed as a traditional process that is no more than minimal processed. Aside from fermentation, the other primary steps involve physical separation and isolation steps that are common in the food manufacturing industry for a variety of food and food ingredients that are widely accepted as "natural."

The reasonableness of finding sodium lactate (from corn) as not more than minimally processed is underscored by past agency decisions finding other ingredients to be no more than minimally processed. For example, the agency has determined that sea salt, "native" corn starch, and a variety of dried spices, including celery powder, meet this criterion. Moreover, minerals, such as potassium chloride, that are mined from the earth and processed by physical means are consistent with the minimal processing requirement.

22/ 71 Fed. Reg. at 70504.

23/ *Id.*

II. FSIS SHOULD NOT COMPROMISE THE SAFETY OF "NATURAL" PRODUCTS

There is no question that FSIS has embarked upon a path that will force food processors to abandon proven, valuable food safety tools in order to qualify for a "natural" claim. It is alarming that FSIS has already taken concrete steps to weaken valuable barriers to potential food safety problems. Consumers should not be forced to choose between "natural" products and safety.

FSIS and food manufacturers have made great strides to control the presence and growth of pathogens and spoilage organisms in all types of meat and poultry products. The optimal use of various natural preservatives depends on a host of factors unique to a given product. Sodium lactate and other ingredients offer an effective food safety-related tool that is vital to the vast majority of the food industry. It is unreasonable that FSIS has notified nearly 30 companies that the intentional use of natural ingredients as antimicrobials prohibits the use of "natural" on food labels.

A. Food Safety is Paramount to Any FSIS Regulatory Policy

Over time, manufacturers of meat and poultry products have promoted a multiple hurdle approach to microbial control. This approach, developed by Felix Leistner of the German Meat Research Institute, focuses on the concept that small, individual barriers to microbial contamination and growth would cumulatively promote food safety more effectively than a single large control measure. Prime examples of the barriers used in the multiple hurdle approach to microbial control include adequate sanitation and quality of raw materials, minimizing the risk of recontamination, formulation of the product to prevent growth of pathogens, refrigeration during distribution, and sanitary packaging measures.

During the last decade, a number of critical ingredients, including sodium and potassium lactate, sodium diacetate, and sodium acetate, have been approved for use in meat and poultry products as effective secondary barriers for control of pathogens and other microbes. 24/ Appropriately, the collective rule authorizing these ingredients was adopted by the agency as an interim final rule to speed their availability and use by food processors.

Food manufacturers have achieved an unprecedented level of food safety through the development and use of tools that inhibit growth of pathogens

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24/ *See e.g.*, "Food Additives for Use in Meat and Poultry Products: Sodium Diacetate, Sodium Acetate, Sodium Lactate and Potassium Lactate," 65 Fed. Reg. 3121 (Jan. 20, 2000).

and other microorganisms. 25/ In particular, the multiple hurdle approach and the *Lm* regulations, discussed below, represent flexible means for controlling pathogens and spoilage organisms that can incorporate a variety of ingredients, methodologies, and innovative technologies. An effective "natural" policy will provide manufacturers of "natural" products with the flexibility necessary to achieve food safety in any manner consistent with the two fundamental requirements of the policy.

B. Sodium Lactate has Established Food Safety Benefits

The food safety benefits of sodium lactate are well-established scientifically and by regulation. It is a valuable secondary barrier for pathogen control that has been adopted widely throughout the food manufacturing industry. Sodium and potassium lactate were introduced as processed meat ingredients to improve safety of products in the mid 1980's. Initially the applications were in uncured poultry and roast beef products and the applications were for an added barrier against potential botulism in cook-in-the-bag (*i.e.* package) uncured roasts. Packaging film technology had progressed at this point to permit production of many cook-in-the-bag products in plastic films rather than metal cans. These products had great consumer and food service industry appeal and a long shelf-life because they were effectively pasteurized to eliminate spoilage organisms and there was no potential for recontamination until the package was opened by the customer.

However, packaging film technology did not directly address the risk from *Clostridium botulinum* (*C. botulinum*) spores that would naturally be in raw meat. Many meat processors embraced the use of sodium and potassium lactate in these products for the purpose of increasing their food safety profile. 26/ This and other steps are deemed prudent as the industry strives to develop ever-improved means to minimize the potential of food safety risk.

25/ In 1999, the Center for Disease Control (CDC) estimated foodborne related illness to afflict as many as 76 million people annually in the United States with Listeria being in the top three as a cause of up to 5000 annual deaths. *See* P.S. Mead *et al.*, "Food-related illness and death in the United States," *Emerging Infect. Dis.* 5: 607-625 (1999). This sparked intense public and governmental pressure on the entire food industry to improve food safety which continues today. Tremendous improvements have been made as reported by the CDC in 2006. *See* CDC, "Preliminary FoodNet data on the incidence of infection with pathogens transmitted commonly through food – 10 states, United States, 2005," *Morbidity and Mortality Wkly Rep.* (*MMWR*) 55: 392-395 (Apr. 14, 2006). Lactate ingredients, including sodium lactate, have made a significant contribution in equipping food processors with a vital tool for maximizing ready-to-eat meat and poultry products.

26/ *See* M.R. Maas, *et al.* "Sodium lactate delays toxin production by Clostridium botulinum in cook-in-bag turkey products," *Appl. Environ. Microbiol.* 55: 2226-2229 (1989).

Further research into the effects of lactate revealed that it also had antimicrobial activity against some other pathogens, most notably *Listeria monocytogenes* (*Lm*). The effect was very dramatic in cured processed meats (nitrite added products) though less so in uncured items. However, it was not widely applied to products until after the large 1998 Listeriosis outbreak that was traced to consumption of cured sliced luncheon meats and hot dogs. 27/

Additional research subsequent to the outbreak confirmed the benefit to public health of using lactate and another synergistically active ingredient, sodium diacetate, in cured processed meats to suppress the potential of *Listeria* growth in processed meats if the product was inadvertently contaminated by this zero-tolerance pathogen. The processed meat industry initiated formula conversions in 2001- 2002 after the research had been validated. 28/ Large Listeriosis outbreaks such as the one in 1998, noted above, have been limited since 2002, in part by use of lactate in a significant proportion of processed meat products. Total cases of Listeriosis also have declined and are approaching the 2010 public health goals established by the Clinton Administration. 29/

The dramatic food safety benefit attributed to the use of lactate and diacetate and the intense activity of the meat industry to reduce the risk of *Listeria* contamination in processed meat products led to the Lm regulations. 30/ During the comment period following the issuance of this interim final rule, FSIS publicly stated that the agency considered the use of lactate/diacetate technology as an

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27/ CDC, "Multistate outbreak of Listeriosis – United States," *Morbidity and Mortality Wkly Rep.* (*MMWR*) 47: 1085-86 (1998).

28/ Although lactate could by itself suppress *Listeria* growth when used at high levels, diacetate was added to the antimicrobial technology to take advantage of synergies between the ingredients. Thus, the combination was employed based on models that were developed and extensively validated. *See* J.R. Sabah, *et al.* "Effect of spices and organic acids on the growth of Clostridium perfringens during cooling of cooked ground beef," *J. Food Prot.* 67: 1840-1847 (2004); J.D. Legan, *et al.* "Modeling the growth boundary of Listeria monocytogenes in ready-to-eat cooked meat products as a function of the product salt, moisture, potassium lactate, and sodium diacetate concentrations," *J. Food Prot.* 67: 2195-2204 (2004); F. Leroi, *et al.* "Effect of salt and smoke on the microbiological quality of cold-smoked salmon during storage at 5°C as estimated by the factorial design method," *J. Food Prot.* 63: 502-508 (2000); and J.H. Schlyter, *et al.* "The effects of diacetate with nitrite, lactate, or pediocin on the viability of Listeria monocytogenes in turkey slurries," *Int'l. J. Food Microbiol.* 19: 271-281 (1993).

29/ *See* CDC, *MMWR*, *supra* note 25.

30/ *See* 68 Fed. Reg. 34207 (June 6, 2003).

example of an Alternative 2 compliance by processors to address the requirements for *Listeria* risk control. 31/

As recently as May 2006, FSIS explicitly discussed lactate in a compliance guidance document and included a selective literature summary. Notably, publications demonstrating inhibition of Listeria growth at less than 2% usage levels, which are considered flavoring applications, are included in the appendix. 32/

As discussed above, barring ingredients that are employed for their antimicrobial properties will affect far more than just sodium lactate. Indeed, it remains uncertain what food safety tools would be available for use in natural products if sodium lactate and other natural preservatives are barred from use in "natural" products.

III. LONG-STANDING "NATURAL" POLICY HAS PROVEN FLEXIBLE AND EFFECTIVE - - RULEMAKING IS UNNECESSARY AND WOULD PROVE UNSUCCESSFUL

A. FSIS "Natural" Policy is Effective Because it Allows for a Flexible Context-Specific Approach

1. FSIS policy must recognize that natural has various meanings and protect consumer expectations accordingly

PURAC is pleased and readily agrees with the agency's observation in the Notice that regulation of "natural" is only possible by considering the context in which the term appears on the food label. The Notice states:

> According to the 1982 policy, the decision of the Agency to approve or deny the use of a "natural"

31/ *See generally*, M. Pierson, "Food safety policy at USDA: the road from an ambitious vision to tangible results," Remarks Prepared for the International Association for Food Protection's 91st Annual Meeting (Aug. 10, 2004), *available at* http://www.fsis.usda.gov/News_&_Events/Speech_081004_Pierson/index.asp.

32/ U.S. Department of Agriculture, Food Safety and Inspection Service, "Compliance guidelines to control Listeria monocytogenes in post-lethality exposed ready-to-eat meat and poultry products," 96-97 (May 2006) *available at* www.fsis.usda.gov/oppde/rdad/FRPubs/97-013F/LM_Rule_Compliance_Guidelines_May_2006.pdf, citing B.K. Bedie, *et al.* "Antimicrobials in the formulation to control *Listeria monocytogenes* postprocessing contamination on frankfurters stored at 4° C in vacuum packages." *J. Food Protect.* 64: 1949-1955 (2001); J.G.K. Samelis, *et al.* "Control of *Listeria monocytogenes* with combined antimicrobials after post-process contamination and extended storage of frankfurters at 4°C in vacuum packages." *J. Food Protect.* 65: 299-307 (2002).

> claim may be affected by the specific context in which the claim is made. For example, claims indicating that a product is "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. However, "all natural ingredients" might be an acceptable claim for such a product. 33/

Context is so critical to regulation of this specific claim due to its varied meanings across diverse categories of food products.

Any definition for "natural" that is adopted by FSIS through policy or regulation must be consistent with consumer expectations for the use of the term. 34/ The common or ordinary meaning of words is often established by the definition in a dictionary. 35/ A typical definition for "natural" is "present in or produced by nature," a broad, generic definition that is likely to have different implications depending on the context in which it is used. 36/ "Natural" terminology is not unfamiliar to consumers. Originating in "health food stores" and other niche markets, "natural" foods are becoming more mainstream as the youthful generation of baby-boomers join the ranks of seasoned consumers with interests in diet, health, and a return to the wholesomeness of foods now featured in several natural and organic retail formats as well as established supermarkets and other retailers.

Aside from the broad definition for "natural," a variety of other dictionary definitions exist for the term "natural" that could apply in food-related contexts. For example, "natural" could mean "of, relating to, or concerning nature," "having a particular character by nature," "free from pretence or artificiality," "not treated, altered, or disguised," "faithfully representing life or nature," or "being a primitive or unregenerate state." 37/ The variety of "natural" products in the marketplace today reflects this reality. The term "natural" is used on meat and poultry products, soaps and cosmetics, produce, dairy products, and breads. Even a well-known beer bears this term.

FSIS has a long standing policy that provides for a context-specific approach to defining and applying the term "natural." The government should not,

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33/ 71 Fed. Reg. at 70504.
34/ *See* 9 CFR § 317.2(c)(1); *see also* 21 CFR §§ 101.3(b) and 102.5(a).
35/ *See United States v. General Foods Corp.*, 446 F.Supp. 740, 744 (1978); *United States v. 44 Cases*, 101 F.Supp. 658, 664 (1951).
36/ Entry for "natural" in *Webster's II New College Dictionary* (Houghton Mifflin Co. 1995) at 729.
37/ *Id.*

and ultimately cannot, try to either capture nor dictate consumer understanding of a term that decidedly does not lend itself to a one-size-fits-all definition.

2. Prior rulemaking efforts failed precisely because a single uniform definition is not practicable

The need for a flexible definition of "natural," such as that found in FSIS's current policy, has been recognized over the past 30 years through the attempts by FSIS, FDA and FTC to define the term by regulation. On each occasion the agency found a uniform, one-size-fits-all definition to be unobtainable notwithstanding persistent efforts to achieve this ultimately unachievable goal.

The FTC was the first agency to attempt rulemaking to define "natural." The agency issued a proposed rule in 1974 to address a variety of food advertising issues, including use of the term natural. In documents associated with the proposed rule, FTC staff recommended the term "natural" should be prohibited, although ancillary factual statements, such as "does not contain any artificial preservatives," should be allowed. 38/ The staff proposal was not adopted by the agency. In 1975, a notice of proposed rulemaking for food advertising issues was reissued, 39/ and FTC initiated a series of extensive public hearings on certain claims, including "natural" the following year. 40/

The FTC hearings led to the November 1978 publication of the Bureau of Consumer Protection's "Staff Report and Recommendations." In reference to the growing administrative record before it, the Staff noted that it was "abundantly clear that there is no generally accepted definition, either regulatory or scientific, which delimits the appropriate use of the term natural as applied to food." 41/ The report further stated "the scope of the problem can be illustrated simply by reference to Webster's Third International Dictionary, which lists 33 definitions for the word 'natural,' at least six of which are applicable to food." 42/ Although it was noted that "a natural food is generally recognized as not containing artificial additives or other artificial ingredients," it was recognized that "the major limitation of the regulatory approach ...is the difficulty in formulating the applicable standards." 43/

38/ *See* "Proposed Trade Regulation Rule; Explanation of Proceeding and Analysis; Statement of Issues; Opportunity to Submit Data, Views or Arguments," 39 Fed. Reg. 39842 (Nov. 11, 1974).

39/ *See* 40 Fed. Reg. 23086 (May 28, 1975).

40/ *See* 41 Fed. Reg. 8980 (Mar. 2, 1976).

41/ "Staff Report and Recommendation, Proposed Trade Regulation Rule on Food Advertising," 16 CFR Part 437, Phase I (Sept. 25, 1978) at 209.

42/ *Id.* at 210.

43/ *Id.* at 226.

Following a decade of rulemaking, the conclusions reached by the FTC are telling. The effort was terminated in 1983, with then-FTC Chairman, James C. Miller III, noting the difficulty of defining the term because "the context in which 'natural' is used determines its meaning." 44/ He further explained: "It is unlikely that consumers expect the same thing from a natural apple as they do from natural ice cream.

The proposed rule assumes, without any evidence, that natural means the same thing in every context." 45/ By extension, recognition that "natural" doesn't mean the same thing in every context dictates the need for, and explains the longstanding regulatory approach, which places a premium on case-by-case review in place of a mandatory, inflexible regulation.

USDA and FDA learned similar lessons when it joined the FTC in holding public hearings in 1978 intended to settle (among other issues) the definition of natural. Public hearings, testimony and a full deliberation produced no call for a formal regulation or further rulemaking. Rather, the following year FDA and USDA announced different approaches to use of the term. FDA stated that it will "not attempt to restrict such claims because it believes that the development and enforcement of standards in this area would be difficult ...." 46/ FSIS opted to review "natural" claims under its pre-market label review program, affording precisely the context-specific review that the agency Notice underscores is of paramount importance. 47/

FDA solicited comments on the use of the term "natural" in the early 1990s as part of the proceedings to implement the Nutrition Labeling and Education Act of 1990 (NLEA). Notwithstanding this interest to once again revisit the possibility of a "natural" regulation, the agency found that "none of the comments provided FDA with a specific direction to follow for developing a

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44/ "Termination of Proposed Trade Regulation: Rule on Food Advertising," 48 Fed. Reg. 23270 (May 24, 1983).

45/ *Id.*

46/ "Food Labeling; Tentative Positions of Agencies," 44 Fed. Reg. 75990, 76012 (Dec. 21, 1979). FDA's decision is not surprising. In supporting documentation, the agency noted its attempts in the early 1970s to develop policy definitions for the use of "natural," which "never progressed enough even for internal guidance, because FDA was unable to arrive at clear cut definitions." FDA, "Food Labeling Background Papers" at 120.

47/ *See id.* This practice, initially memorialized in 1982 in Policy Memorandum 055, continues to this day. U.S. Department of Agriculture, Food Safety and Inspection Service, "Policy Memorandum 055: Natural Claims," (Nov. 22, 1982).

definition ..." 48/ This conclusion has been reaffirmed as recently as 2005 when the agency denied consideration of a citizen petition to define "natural." In its response letter to the petitioner, FDA stated: "You have not provided us with any information that wasn't considered in issuing our final rule in 1993 that would assist us in developing a definition regarding the use of the term 'natural,' thereby allowing us to move away from our current policy." 49/

Thirty years of regulatory interest and effort has not produced a regulation because the term has a variety of meanings depending on the context in which it was used and because a flexible policy approach provided ample guidance on how the term should be used. FSIS should heed the lessons learned from these past failures to adopt one-size-fits-all formal regulation and continue to apply the term "natural" via its time-tested, flexible, and effective policy approach.

3. There are substantial disadvantages of a static regulation

There are significant drawbacks to FSIS's decision to define "natural" by regulation. The definition of a regulated term commonly proves to be unworkable because the definition does not provide for the flexibility to accommodate new developments associated with the term. Of primary concern, the definition cannot be effectively amended as needs permit because of the inherent time-consuming nature of the rulemaking process. Notice and comment rulemaking typically takes 18 to 24 months to complete under the best of circumstances. It is unlikely that FSIS could devote (nor should it devote) the resources necessary to keep a "natural" regulation current.

Food labeling claims also create economic incentives to manufacturers for their use. In short, manufacturers try to readily develop products that meet consumer demands. The policy approach for use of the term "natural" adopted by both FSIS and FDA provides for the context-specific analysis of its use and has allowed for the development of an increasing number of "natural" products in the marketplace over the last 25 years as consumer interest in these products has increased. Confining "natural" within a static regulatory definition would unduly restrict the development of meat and poultry products able to bear a "natural" claim, thereby severely curtailing the economic incentives to develop new food products sought by consumers.

48/ "Food Labeling: Nutrient Content claims, General Principles, Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food," 58 Fed. Reg. 2302, 2407 (Jan. 6, 1993).
49/ Letter from Margaret O'K. Glavin, Associate Commissioner for Regulatory Affairs, FDA, to Antonio Zamora (Dec. 12, 2005).

B. Abrupt Shift in Policy in Response to Petition Lacks Rational Basis

The Petitioner makes two assertions in support of its request to FSIS to define "natural" by regulations and alter the August 2005 "natural" policy in the interim: (1) consumers are confused by current usage of the term "natural" and want it defined by regulation, and (2) a regulatory definition for "natural" would provide consistency for its use. Neither of these assertions are true or supported by the Petition. Even before public comment was requested, FSIS unwisely acted in a manner that has effectively granted significant portions of the action requested by the Petition.

1. Petition fails to establish consumer confusion as basis for new regulation

Throughout the Petition, the Petitioner contends consumers are confused by the use of the term "natural." The Petitioner states: "Consumers are confused as to the specific meaning [of natural] ...;" 50/ but no evidence is presented to support this statement. The Petitioner then quotes FDA stating "that uses of 'natural' claims are confusing and misleading to consumers and frequently breach the public's legitimate expectations about their meaning." 51/ However, this statement was made by FDA in its 1991 proposed rulemaking on "natural," which in turn relies upon statements about consumer confusion made by the staff of the FTC in the late 1970s and early 1980s. 52/ The dated nature of this statement and lack of any additional evidence regarding consumer understanding of "natural" do not suggest that today's consumers are confused about the meaning of the term.

The Petitioner states: "On the other side of this interest in food labeling, however, is continued consumer confusion regarding the meaning of 'natural.'" 53/ The citation for this statement is an article that discusses the term "organic" and offers no support to the claim that consumers are confused by the meaning of "natural." The Petitioner further notes: "Consumer research continues to report confusion among consumers as to the meaning of 'natural' ...." 54/ The Petitioner appears to attribute this statement to a 2002 survey conducted by the National Consumers League (NCL), but the survey merely reflects that consumers view the term "natural" differently depending on the context in which it is used. Finally, the Petitioner states: "Consumers are confused and mistrustful." 55/ Once again, no evidence is proffered in support of this statement.

50/ Petition at 4.
51/ *Id.* at 5.
52/ *See* Petition at 5; 56 Fed. Reg. 60421, 60466 (Nov. 27, 1991).
53/ Petition at 6.
54/ *Id.* at 7.
55/ *Id.* at 12.

Moreover, the Petitioner asserts that consumers seek greater federal regulation of the term "natural" and that they want the federal agencies to engage in formal rulemaking on the subject. For instance, the Petitioner notes

> 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. 56/

The Petitioner also references a consumer survey in a petition submitted to FDA by the Sugar Association, which requested that agency to adopt the FSIS "natural" policy in place of its own. The Petitioner states "That survey concluded 83% of respondents thought the agencies should implement rules governing 'natural' label claims." 57/

It is difficult to fully evaluate these statements and characterizations as the NCL study is not included with the petition nor is it otherwise publicly available. It is possible that the survey asked only "if" there was a need for federal oversight of "natural" and not "how" such oversight should take place or in what fashion a policy or regulation should be maintained. The resulting data fail to explain the extent of consumer knowledge regarding the current role the agencies play in regulating use of the "natural" claim, and it is not clear what government involvement is sought by respondents. The Sugar Association survey similarly asks consumers if there should be government oversight, not whether there is a compelling need or in what way the term "natural" should be regulated.

While the Petition frames the need for government rulemaking in terms of consumer protection, the Petition fails to establish an empirical basis for the requested action. FSIS has, as a result, unwittingly made significant changes to its "natural" policy without a basis for doing so. Moreover, the questions properly considered by the agency relate to the "how" not "if" of "natural" claims regulation. Against the backdrop of a context-specific approach, and the failure of previous attempts at rulemaking, FSIS should remain mindful of what works and what does not.

56/ *Id.* at 7.
57/ *Id.* at 8.

2. Petition would not create consistent "natural" policy nor is such perfect consistency desirable or necessary

The Petitioner alleges "The August 2005 change to the ... Natural Policy renders the policy's guidance internally inconsistent and creates confusion ..." and "the interests of consumer protection and confidence require clarity and certainty in the use of the word 'natural' on product labeling." 58/ In fact, the August 2005 policy is consistent with the "natural" policy as it has been applied in practice by FSIS for years – a policy in which ingredients were considered on a case-by-case basis when appropriate. Critical of the current context-specific approach long in place, the Petition recommends an approach riddled with inconsistency. Furthermore, the Petitioner's criticism of the so-called "inconsistencies" in the August 2005 policy falls flat because the proposed framework for defining "natural" contains numerous contradictions and inconsistencies, as well.

The Petitioner takes issue with the two modifications FSIS makes in the 2005 "natural" policy that explicitly provide for the use of sodium lactate (from corn) and ingredients on the National Organic Program's National List in products bearing a "natural" claim. The Petitioner alleges that these provisions "create inconsistency within the Policy and, consequently, the potential for consumer confusion and erosion of the significance of the natural claim." 59/ Specifically, the Petitioner argues that the use of sodium lactate, which has antimicrobial properties at any use level, contradicts the policy's prohibition on chemical preservatives, while the use of any ingredient on the National List, which includes a limited variety of synthetic ingredients, is at odds with the policy's prohibition of such substances.

However, the two modifications to the policy noted by the Petitioner do neither significantly change the 1982 policy it replaces nor add new inconsistencies. In fact, the August 2005 policy revision only serves to memorialize FSIS's application of the policy prior to this date. We reiterate the agency's explanation:

> FSIS modified the guidance on occasion to make it consistent with prevailing policies, to reflect case-by-case decisions made by the Agency, and to update references to regulations. In August 2005, FSIS modified the guidance by acknowledging that sugar, sodium lactate (from a corn source), and natural flavorings from oleoresins or extractives

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58/ *Id.* at 1.
59/ *Id.* at 3.

could be acceptable for products bearing 'natural' claims. 60/

In addition, the 1982 policy had a variety of exceptions to the two fundamental requirements for a "natural" claim. These include the allowance, on a case-by-case basis, of ingredients in a "natural" product that are more than minimally processed but do not significantly change the character of the product and the recognition that the decision to approve or deny the use of a "natural" claim is context-specific.

The Petitioner seeks to propose a rigid framework for defining "natural," but the proposal includes a variety of exceptions and inconsistencies, as well. First, throughout its discussion of the issues and it proposed policy, the Petitioner never defines the terms "chemical preservative," "natural preservative," "preservative," and "antimicrobial" and uses them as synonyms on the one hand and to delineate differences between ingredients on the other. Second, the Petitioner's proposed policy contains not only the prohibition on chemical preservatives that is part of the existing policy but also states "Beyond the definition of 'chemical preservative' ... 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." 61/ While sodium lactate specifically is called out as possessing such antimicrobial properties, this language used by the Petitioner would seemingly indict all natural preservatives, whether or not they are exempted from the FDA's definition of "chemical preservative," which is incorporated by reference in FSIS's "natural" policy.

Third, a categorical exemption is written into the Petitioner's policy that provides for the 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." 62/ Stated examples of such ingredients are (but not limited to) calcium silicate, magnesium oxide, calcium carbonate, dimethylpolysiloxane, and sodium aluminosilicate. The apparent rationale for this categorical exemption includes the assertion that "[p]rocessing aids, such as anticaking or antifoaming agents, have functions in foods that are considered to be physical rather than chemical," 63/ a distinction that is not found in the existing policy and whose basis is unclear.

Finally, the Petitioner appears to support the minimal processing requirement of FSIS's long-standing "natural" policy, but positions the Petition to allow for "any technological means of qualifying foods for use of the claim. This

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60/ 71 Fed. Reg. at 70504.
61/ Petition at 13-14.
62/ *Id.* at 14.
63/ *Id.*

allows for the use of new technologies, especially advances in minimal processing, to create maximum flexibility." 64/ We find it intriguing – and notably inconsistent – that the Petitioner seeks "to create maximum flexibility" with regard to the minimal process requirement of the "natural" policy while seeking a rigid restriction against ingredients that possess antimicrobial properties, regardless of whether they are "natural or chemical." 65/

In summary, there are no compelling reasons for FSIS to deviate from its current "natural" policy and approach to regulating the use of such claims. No issues of product safety have arisen through use of the policy. There is no indication of contemporary consumer confusion regarding products bearing a "natural" claim. There is no evidence that consumers are suffering from economic fraud when purchasing "natural" products. Thus, moving from the existing policy approach to a "natural" term defined by regulation is not justified.

IV. FSIS LACKS BASIS FOR SIGNIFICANT SHIFT IN NATURAL POLICY

A. FSIS Has Failed to Articulate Justification for Policy Reversal

As noted previously, FSIS has failed to adequately explain why sodium lactate is at odds with its long-standing "natural" policy and why it has chosen to rescind its 2005 policy modification that explicitly allowed sodium lactate (from corn) in products bearing this claim pending the completion of rulemaking. FSIS states "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.'" 66/ The agency adds "The value and integrity of the 1982 policy is challenged ... by new uses of ingredients that have previously been used for flavoring purposes, for example, as antimicrobial agents. While the food safety purpose of using antimicrobial agents is important, their effects raise questions as to whether they can be used in products labeled 'natural.'" 67/ No further explanation of the agency's action is offered.

This abrupt change in the "natural" policy comes as an unwelcome surprise to PURAC and other companies in the food ingredient and manufacturing industry. Many companies in the industry have significant investments in "natural" product lines and rely heavily on the policy FSIS followed with respect to this term up to its recent reversal. Threatened revocation of label approvals and

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64/ Petition Exhibit A at 1.

65/ Please recognize that PURAC is not commenting on the substantive merits of the Petitioner's proposal regarding minimal processing. Instead, we disagree with the Petitioner's call for rulemaking in order to achieve consistency in defining "natural" because a one-size-fits-all approach to this term is not possible.

66/ 71 Fed. Reg. at 70504.

67/ *Id.*

the premature shift in policy has inflicted needless injury and uncertainty for these firms.

The actions undertaken by FSIS even before the rulemaking process was announced underscores the danger of government action ahead of input from all stakeholders. The industry values the open exchanges it has with FSIS prior to the agency taking action that would severely affect its business and/or manufacturing practices. The fact that the agency did not engage the industry in dialogue prior to making this change calls into question the manner in which FSIS has addressed the sodium lactate issue to date and frustrates the desire of industry stakeholders to furnish meaningful comments to the agency. Regardless of whether rulemaking is undertaken, FSIS should not revoke label approvals or take any other action contrary to its 2005 "natural" policy.

B. FSIS Has Not Been Presented with Any New Information that Warrants Change in Allowance of Sodium Lactate in "Natural Products"

Respectfully, there is no information not previously known to FSIS that warrants or justifies the decisions reflected in the Notice. The information purportedly received by FSIS – "that sodium, potassium, and calcium lactate salts provide an antimicrobial effect at levels that have been regulated as providing a flavor effect" (*i.e.*, up to 2.0 percent of a product formulation) 68/ – has, in fact, been known by the agency for over 14 years and is in the public record created by its past rulemakings.

FSIS first approved sodium lactate and potassium lactate in 1993. In the final rule implementing this regulation, FSIS provided for the use of sodium lactate and potassium lactate as flavor enhancers and flavoring agents at levels not to exceed 2.0 percent in various meat and poultry products. 69/ As reflected by the comments on the proposed rule outlined in the preamble, a number of parties criticized the agency for limiting the regulation of lactates to its flavor attributes and questioned why its antimicrobial properties were not addressed.

A processor who opposed the proposed rule "believes that the primary purpose of using lactate salts is to improve food safety by retarding growth of common spoilage bacteria. This processor stated that the secondary effects are as a flavor enhancer or flavoring agent." 70/ A trade group "objects to the proposed use of these substances as flavor enhancers and flavoring agents in meat and poultry

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68/ U.S. Department of Agriculture, Food Safety and Inspection Service, "Natural Claims," *supra* note 4.

69/ "Use of Potassium Lactate and Sodium Lactate as Flavoring Agents in Various Meat and Poultry Products," 58 Fed. Reg. 4067 (Jan. 13, 1993).

70/ *Id.* at 4069.

products and requests that the proposed regulation either be modified to recognize that lactates are being used for their preservative characteristics or be withdrawn." 71/

A university provided a summary of research data documenting the flavoring enhancing characteristics of sodium lactate. "These research data also document the use of sodium lactate in limiting microbial growth in cooked, whole muscle beef top round roast. This university strongly supports either the incorporation of the 'antimicrobial' benefits into the current ruling or the drafting of a second proposed rule which documents the use of potassium lactate and sodium lactate as a means of controlling microbial growth." 72/ And finally, among the concerns noted by three food ingredient companies opposing the rule were: "(1) The primary intended effect of sodium lactate is extended shelf life, even possible storage without refrigeration; ...[and] (4) the proposed rule does not recognize the most common use of lactates which is as an antimicrobial agent to reduce undesirable microorganism growth ...." 73/

Leaving aside that FSIS elected not to substantially change the scope of the final rule based on these comments, it is clear that the antimicrobial properties and benefits of sodium lactate at levels below two percent are widely known. The value of the antimicrobial attributes of these ingredients was affirmed in subsequent rulemaking expressly approving these ingredients at higher levels to maximize effectiveness as antimicrobials in certain applications. Indeed, the regulation is framed as allowing "up to" 4.8 percent of these ingredients, meaning, of course, that any amount below this level (including below two percent) is permitted and recognized to have an antimicrobial affect.

It is disingenuous for FSIS to state it was unaware of the antimicrobial attributes of lactates at levels below two percent. More importantly, as explained above, sodium lactate fully complies with the two-prong natural policy and, therefore, the agency acted without a rational basis in recently switching its position. On substantitive and procedural grounds, FSIS has acted with disregard to the value of its established "natural" policy in protecting consumer expectations that arise depending upon the context of a "natural" claim.

V. ECONOMIC IMPACT OF THE PETITION

By prohibiting the use of sodium lactate in "natural" products and appearing to limit the options for pathogen control and preservation to high pressure processing (HPP) or other expensive processing techniques, the policy

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71/ *Id.*
72/ *Id.*
73/ *Id.*

proposed by the Petition would result in significant economic impacts on meat and poultry product manufacturers, ingredient suppliers, and consumers.

A. The Petition Limits Affordable Options for Pathogen Control and Preservation

The Petition is drafted in a manner that prohibits the use of sodium lactate and other relatively inexpensive dual or multi-use ingredients that exert antimicrobial properties and appears to favor HPP technology. Thus, in limiting the food safety tools for "natural" products, this high cost option may be one of the few available to food processors.

HPP is a technology-intensive method of food processing where food is subjected to pressures greater than 80,000 pounds per square inch – or approximately 6,000 atmospheres – to achieve microbial inactivation. Products containing no air spaces are packaged in flexible containers, placed into a high pressure chamber filled with a type of hydraulic fluid (normally water), and pressurized for several minutes. The uniform pressure exerted through the hydraulic fluid allows the product to maintain its form and sensory and nutritional qualities while vegetative bacteria are inactivated. 74/

The capital cost of HPP ranges from $500,000 to $2.5 million or more, depending on capacity, extent of automation, and other infrastructure changes necessary to accommodate this heavy equipment. The high cost of this technology presents a formidable economic barrier for food manufacturers, particularly small or mid-sized companies, to obtain this means of microbial control.

HPP is also a relatively new technology. Its full benefits and limitations are not as fully understood as existing food safety tools that are commonly employed using sodium lactate and many other natural ingredients that act as antimicrobials/preservatives. High pressure processing does not kill *Clostridium botulinum* spores unless high temperatures are also employed. 75/ High pressure resistant strains of *Listeria monocytogenes* have also been found, and their existence needs to be carefully considered in applications of this technology. 76/

74/ *See* Ohio State University Extension Fact Sheet, Food Science and Technology, "High Pressure Processing," available at http://ohioline.osu.edu/fse-fact/001.html (accessed on Dec. 18, 2006).

75/ D. Margosch, *et al.* "Comparison of pressure and heat resistance of *Clostridium botulinum* and other endospores in mashed carrots," *J. Food Prot.* 67: 2530-7 (2004). Erratum in: *J. Food Prot.* 68: 2502 (2005).

76/ A. Tay, *et al.* "Pressure death and tailing behavior of Listeria monocytogenes strains having different barotolerances," *J. Food Prot.* 66: 2057-61 (2003).

B. Petition Would Impose Significant Costs on All Parties Involved

The Petitioner asserts that the rescission of the wholesale exemption for sodium lactate "will avoid adverse economic impacts to manufacturers that use the exemption to gain a market niche, only to have their 'natural' status revoked when a new rule is promulgated." 77/ Such statements completely ignore the fact that these adverse impacts, as described below, actually will occur now if the interim policy proposed by the Petitioner is adopted and not when a final rule is issued.

For product manufacturers, significant economic impacts would be associated with the rescission of existing label approvals. Existing label stock would have to be discarded and new labels printed, affected products would have to be reformulated, and the investment made in "natural" products under development would be lost. In addition, the need for capital investment for new processing techniques, such as HPP, would have to be considered if reformulation was not possible. For example, the estimated cost to use sodium lactate is 1.7-2.5 cents per pound of finished product, lemon juice/vinegar is 3.5-5 cents, HPP is 10-25 cents, and thermal post pasteurization is 12-20 cents. 78/ These additional costs will be passed along to customers unnecessarily and may result in some segments of the population being unable to afford "natural" products.

For ingredient suppliers, there are significant costs associated with losing lines of ingredients that are currently marketed or under development for use in "natural" products that complied with the 2005 policy. The economic impacts are much more significant if it is recognized that the "natural" foods market is poised to maintain double-digit growth over the next few years, and lactates figured to be a critical food safety ingredient in a large proposition of these new products.

Finally, for all segments of the food manufacturing industry, the uncertainty inherent in any interim policy FSIS will apply from now until the rulemaking process is concluded will stifle product development and associated capital investment.

VI. CONCLUSION

FSIS has allowed and should continue to permit the use of sodium lactate in "natural" products via its long-standing, flexible policy that provides for the case-by-case assessment of the term. Sodium lactate is not a chemical preservative and is derived by no more than minimal processing from a natural, renewable source. Sodium lactate and other natural preservatives are vital and

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77/ Petition at 16.

78/ Ohio State University Extension Fact Sheet, Food Science and Technology, "High Pressure Processing," *supra* note 74.

effective food-safety tools, particularly for the control of pathogens. There is no legal or factual basis to exclude these ingredients that enhance the safety and quality of numerous "natural" meat and poultry products.

The recent actions taken by the agency to prohibit the use of sodium lactate and other natural preservatives in "natural" products are premature and ill-considered. The Petition referenced by FSIS falls well short of providing even a colorable basis for the action requested and provides no new information to FSIS. FSIS has failed to adequately explain why these ingredients conflict with its long-standing "natural" policy and why it has rescinded, pending the completion of rulemaking, the explicit allowance of sodium lactate (from corn) in products bearing this claim.

The variable, context-specific meaning of "natural" has and will again doom attempts to establish a single, one-size-fits-all regulation. Procedurally, FSIS unwittingly proceeded prematurely in taking the actions requested by the Petitioner. The result – effectively removing sodium lactate as a proven, valued food safety tool – runs contrary to the agency's food safety mission.

PURAC urges FSIS to return to its well-received August 2005 policy and continue to protect consumers from misleading "natural" claims via its prior approval process. The quality of the agency's decision-making is tied to the input of all interested parties. Upon review of the administrative record created in response to the Notice, we urge FSIS to consider the need for rulemaking and any other changes in an open, transparent fashion.

Respectfully submitted,
PURAC America, Inc.

Gerrit Vreeman
President