Lactic Acid, Sodium Lactate, and Potassium Lactate
Handling/Processing

Identification of Petitioned Substance

Chemical Names:
1. Lactic Acid
2. Sodium Lactate
3. Potassium Lactate

Other Names:
1. Lactic Acid, 2-hydroxypropanoic acid, 2-hydroxypropionic acid
2. Sodium Lactate, sodium 2-hydroxypropanoate
3. Potassium Lactate, potassium 2-hydroxypropanoate

Trade Names:
Purac® Lactic Acid, (Purac, Fit Plus, Fit Plus 90), Purasal®S Sodium Lactate, Purasal® Powder S, Purasal® HiPure P Plus Potassium Lactate, Purasal® Lite (sodium/potassium lactate blend) ARLAC P ® (Potassium Lactate FCC) ARLAC S ® (Sodium Lactate FCC) (AMD) Lactic Acid 50% FCC, ADM Lactic Acid 88% USP Heat Stable (fermented), ADM Lactic Acid, 88% FCC

CAS Numbers:
1. Lactic Acid: 50-21-5 (L-: 79-33-4; D-: 10326-41-7; DL-:598-82-3)
2. Sodium Lactate: 72-17-3
3. Potassium Lactate: 996-31-6

Other Codes:
1. Lactic Acid: INS number 270, E number E270, EC number 200-018-0, FEMA number 2611
2. Sodium Lactate: INS number 325, E number E325, EC number 201-196-2
3. Potassium Lactate: INS number 326, E number E326, EC number 233-713-2

Summary of Petitioned Use

Lactic Acid
Lactic acid is listed at 7 CFR Part 205.605 (a) as an approved nonsynthetic material for use in products labeled as "organic" or "made with organic (specified ingredients of food group(s))."It appears in "Acids (Alginic; Citric—produced by microbial fermentation of carbohydrate substances; and Lactic)."There are no other specific restrictions on how lactic acid may be used in the organic regulations. This report will also address the lactic acid salts, sodium lactate and potassium lactate, that were petitioned for inclusion on the National List at §205.605(b) in 2004.

Lactic acid can also be produced synthetically via the hydrolysis of lactonitrile; however, the synthetic form of lactic acid will not be discussed in this document. For the purpose of this report, only the nonsynthetic form of lactic acid will be reviewed because that is the only form that is listed on the National List.

Sodium Lactate and Potassium Lactate
On June 25, 2014, the NOP issued a memorandum to the National Organic Standards Board (NOSB) stating the following:

- *On January 5, 2004, NOP received a combined petition for the substances sodium lactate and potassium lactate for use in organic handling. The petitions requested the addition of sodium lactate and potassium lactate to section 205.605 of the National List.*
- *On January 22, 2004, the NOP notified the petitioner that the petitions were not necessary since the materials were formulated products derived from blending substances already included on the National List.*
- *NOP understands that interpretation is not consistent with previous NOSB Recommendations on classification of materials and there is some confusion in the organic industry regarding the regulatory status of these two materials as well as other lactate salts, such as calcium lactate. In response to these questions,*

NOP requests that the NOSB take up the petitions for sodium lactate and potassium lactate for consideration for inclusion on the National List. (McEvoy 2014)

The original 2004 petition was submitted for the following use: "Both Sodium Lactate and Potassium Lactate are used in meat processing as a pathogen inhibitor. Product comes as a liquid and is added to meat as an ingredient at the rate of 1% to 4.8% as prescribed by USDA-FSIS regulations, depending on the product. Whether one uses sodium lactate or potassium lactate is at the discretion of the processor or by the requirements of the recipe - i.e. Low sodium products" (Applegate Farms 2004).

Characterization of Petitioned Substance

<u>Composition of the Substance:</u>

Lactic Acid

The structural formula of lactic acid is:

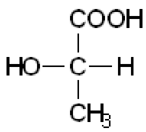

Figure 1: The structural formula of lactic acid

Lactic acid is 2-hydroxypropionic acid. Lactic acid occurs naturally in two optical isomers, D(-) and L(+)-lactic acids. Since elevated levels of the D-isomer are harmful to humans, L(+)-lactic acid is the preferred isomer in food and pharmaceutical industries (Vijayakumar, Aravindan and Viruthagiri 2008). Lactic acid is a colorless, syrupy liquid or white to light yellow solid or powder (Joint FOA/WHO Expert Committee on Food Additives (JECFA) 2004). The Food Chemicals Codex specifies that food grade lactic acid should contain not less than 95% or more than 105% of the labeling concentration (Life Sciences Research Office 1978). Lactic acid is commercially available at different grades (qualities). They include technical grade lactic acid (20 -80%), food grade lactic acid (80%), pharmacopoeia grade lactic acid (90%), and plastic grade lactic acid. Pharmaceutical and food grade lactic acids are considered to be most important in the lactic acid production industry.

Sodium Lactate

The structural formula for sodium lactate is:

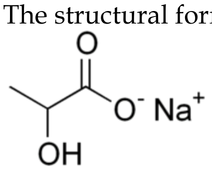

Figure 2: The structural formula of sodium lactate

Sodium lactate is hygroscopic. It is derived from natural L(+) lactic acid, a weak acid having a dissociation constant of 1.389.10-4 at 22°C (pKa=3.857).Sodium lactate has a content of 59-61% (w/w) and a stereochemical purity (L-isomer) of at least 95% (Houtsma 1996).

Potassium Lactate

The structural formula is:

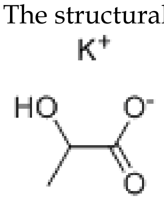

Figure 3: The structural formula of potassium lactate

Potassium lactate is an anhydrous, clear, hygroscopic and syrupy solution, which complies with Food Chemical Codex V. It has a lactate content of 59-61% (w/w), a stereochemical purity (L-isomer) of at least

95%, a pH of 6.5 – 8.5, and a concentration of 60% solids by weight in purified water. The crystalline potassium salt of lactic acid is hygroscopic and extremely difficult to isolate (Joint FAO/WHO Expert Committee on Food Additives (JECFA) 2003).

Source or Origin of the Substance:

Lactic Acid

Lactic acid is produced by the fermentation of natural food sources such as dextrose (from corn) and sucrose (from sugarcane or sugar beets) or starch (from barley, corn, malt, potato, rice, tapioca or wheat). The substrate is fermented to lactic acid by food grade microorganisms. During the fermentation process, the pH is kept at a constant value by the addition of lime/chalk (calcium carbonate), which neutralizes the acid and results in the formation of calcium lactate. For the purification process, after fermentation has ended, the calcium lactate-containing broth is generally heated to 70 °C to kill the bacteria, filtered to remove cells, carbon-treated, evaporated, and acidified with sulfuric acid to pH 1.8 to convert the salt into lactic acid. The by-product, insoluble calcium sulfate (gypsum), is removed by filtration.

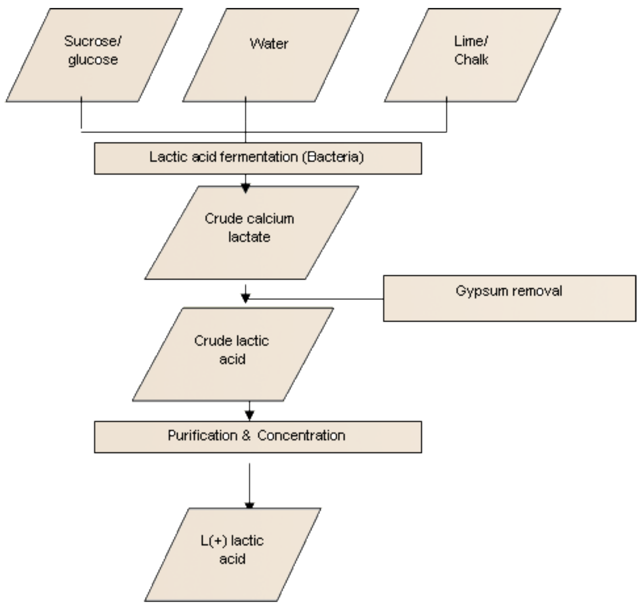

Figure 4 – Lactic Acid Production (Corbion Purac 2014)

Sodium Lactate and Potassium Lactate

Sodium and potassium lactates are generally produced from natural (fermented) lactic acid, which is then reacted with sodium hydroxide and potassium hydroxide, respectively (Houtsma 1996).

Properties of the Substance:

Lactic Acid

Lactic acid is a viscous, nonvolatile liquid at room temperature, soluble in water and miscible in alcohol (Life Sciences Research Office 1978). Additional properties are outlined in Table 1 below:

Table 1: Physical and chemical properties of lactic acid (Corbion Purac 2014)

Molecular Weight	90.08
Physical appearance	aqueous solution
Taste	mild acid taste
Melting point	53°C / 127°F
Boiling point	> 200°C / 390°F
Solubility in water (g/100 g H_2O)	miscible
Dissociation Constant, Ka	1.38 * 10^ -4

pKa	3.86
pH (0.1% solution, 25°C)	2.9
pH (0.1 N solution, 25°C)	2.4

Sodium Lactate

Sodium lactate's properties are outlined in Table 2 below:

Table 2: Physical and chemical properties of sodium lactate (World of Chemicals 2014)

Molecular Weight	112.06 g/mol
Physical appearance	Colorless liquid (reagent grade) or slightly yellowish (edible-grade
Taste	mild saline taste
Density	1.33 g/cm^3
Refractive	1.422-1.425 n20/D
Solubility in water (g/100 g H_2O)	miscible

Potassium Lactate

Properties of potassium lactate are outlined in Table 3 as follows:

Table 3: Physical and chemical properties of potassium lactate (World of Chemicals 2014)

Molecular Weight	128.17 g/mol
Physical appearance	Clear, colorless liquid
Taste/odor	Odorless or with a slight characteristic odor
Solubility in water (g/100 g H_2O)	viscous

<u>Specific Uses of the Substance:</u>

Lactic Acid

Lactic acid appears on the National List, 7 CFR Part 205.605(a), without an annotation. Lactic acid is widely used in almost every segment of the food industry, where it carries out a wide range of functions. The major use of lactic acid is in food and food-related applications, which in the U.S. accounts for approximately 85% of the demand. The other uses are non-food industrial applications. Lactic acid occurs naturally in many food products. It has been in use as an acidulant and pH regulator for many years. It regulates microflora in food and has been found to be very effective against certain types of microorganisms, giving it pronounced efficacy as a preservative (Vijayakumar, Aravindan and Viruthagiri 2008).

Common uses include, but are not limited to:

1. In sugar confectionery, it is used in continuous production line for high boiled sweets to make perfectly clear sweets with minimum sugar inversion and with no air trapped.
2. In bakery products it is used for direct acidification of bread.
3. It increases butter stability and volume.
4. It produces a mild and pleasant taste in acid pickles, relishes and salad dressings.
5. Lactic acid suppresses Coliform and Mesentericur groups of bacteria.
6. It is used in jams, jellies and frozen fruit desserts.
7. In dairy products such as cottage cheese, the addition of lactic acid is preferred to fermentation.
8. Used in imitation dairy products such as cheese and yogurt powder.
9. Lactic acid is widely used in preserving fruits, for example helping to maintain firmness of apple slices during processing. It also inhibits discoloration of fruits and some vegetables.

10. Use of buffered[1] lactic acid improves the taste and flavor of many beverages, such as soft drinks, mineral water and carbonated fruit juices.
11. In breweries, lactic acid is used for pre-adjustments during the mashing process and during wort cooking.
12. Acidification of lager beer with lactic acid improves the microbial stability as well as flavor.
13. It is used in processing of meal in sauces for canned fish, to improve the taste and flavors and to mask amine flavor from fish meal.

(Vaishnavi Bio-Tech Limited 2011)

Lactic acid is also marketed for a myriad of other non-food applications. These include, but are not limited to, use as an industrial chemical, as an acidulant, in pharmaceutical, leather, and textile industries, and as a chemical feedstock. Another application of lactic acid is its use for biodegradable and biocompatible lactate polymers, such as polylactic acid (Vijayakumar, Aravindan and Viruthagiri 2008).

Sodium Lactate and Potassium Lactate

Sodium and potassium lactate were petitioned for use as pathogen inhibitors for processed meat. The 2004 petition explains that "whether one uses sodium lactate or potassium lactate is at the discretion of the processor or by the requirements of the recipe - i.e. Low sodium product." (Applegate Farms 2004). The main argument in the petition is that sodium and potassium lactates are some of the few known antimicrobials for meat products that are recognized by the USDA Food Safety and Inspection Service (USDA-FSIS) to inhibit growth of *Listeria monocytogenes*, along with *E.coli*, *Salmonella* and other pathogens. Sodium and potassium lactates can replace nitrates/nitrites in meat products and are generally recognized as safe (GRAS).

The petition states that the USDA-FSIS declared in 9 CFR Part 430, "Control of *Listeria monocytogenes* in Ready-to-Eat (RTE) Meat and Poultry Products; Final Rule" that "On the question of a 'Zero Tolerance' for *L. monocytogenes* and particularly with respect to RTE products that support growth of the pathogen, FSIS currently regards any amount of the organism as a product adulterant." Therefore, sodium and potassium lactate can be used during the production of RTE meat and poultry products to remain in compliance with the USDA-FSIS requirements.

In addition, sodium lactate and potassium lactate are permitted in the U.S. as flavoring agents in meat, poultry and food products, and as emulsifiers, flavor enhancers, adjuvants, humectants and pH control agents. (Purac 2011)

An increase in sodium lactate levels from 0-4% in cooked beef roasts was found to result in a darker red color with less gray surface, and improved juiciness and tenderness of the meat product (Houtsma 1996).

Approved Legal Uses of the Substance:

Lactic Acid

Lactic acid is a "Direct Food Substance Affirmed as Generally Recognized As Safe," or GRAS, as an antimicrobial agent, curing and pickling agent, flavor enhancer, flavoring agent and adjuvant, pH control agent, and as a solvent and vehicle, with no limitation other than current good manufacturing practice according to FDA regulations at 21 CFR 184.1061.

Sodium Lactate

Sodium lactate is affirmed as GRAS at 21 CFR 184.1768 for use in food with no limitation other than current good manufacturing practice. However, the FDA does not authorize its use in infant foods and formulas.

[1] Buffered lactic acid may include materials that are not listed as approved on the National List of Allowed and Prohibited Substances.

Potassium Lactate

Potassium lactate is affirmed as GRAS at 21 CFR 184.1639 for use in food with no limitation other than current good manufacturing practice. However, the FDA does not authorize its use in infant foods and formulas.

Action of the Substance:

Lactic Acid

Lactic acid has a low pH (approximately 3-4). It is a weak acid, which means that it only partially dissociates in water.

In meat products, it can be used as an antimicrobial agent. Alakomi, et al. (2000) suggest that the antibacterial action of lactic acid is largely due to its ability in the undissociated form to penetrate the cytoplasmic membrane of the pathogen, resulting in reduced intracellular pH and disruption of the transmembrane proton motive force. Lactic acid can cause sublethal injury for gram-negative bacteria and is a potent outer membrane (OM)-disintegrating agent, causing the lipopolysaccharide layer release, which sensitizes bacteria to detergents and lysozyme. While the OM damage occurs with acids of a pH of 4 (i.e., dissociable acids) the additional OM-disintegrating effect of lactic acid is said to be due to the action of undissociated lactic acid molecules. At a pH of 3.6 to 4, between 40% and 60% of the lactic acid molecules are present in the undissociated form. Damage to the OM of the bacteria, as a result of lactic acid, enables the antimicrobial activity of other components against gram-negative bacteria (Alakomi, et al. 2000). In addition, lactic acid has been found to be more effective than chlorine treatments of raw meat in poultry processing facilities. When chlorine reacts with organic materials, it can easily and quickly lose effectiveness, thereby requiring careful monitoring for appropriate replenishment. The antimicrobial action of lactic acid was found to outlast that of chlorine (Killinger, et al. 2010).

Its acidic nature imparts a mellow and lasting sourness to many products including confectionery, and it is used not only for the sharp flavor, but also to bring the pH of the cooked mix to the correct point for setting. In beer production, lactic acid improves the microbial stability and also enhances the sharp flavor of beer during the manufacturing process(Vijayakumar, Aravindan and Viruthagiri 2008).

Lactic acid is used as an acidulant in flavored soft drinks and fruit juices and has been found to stabilize natural colors in beverage products, which are generally unstable in nature. According to Corbion Purac (2013), lactic acid added to beverages in place of citric acid can increase color stability by up to 50%. Natural colors such as anthocyanins (natural red-purple) are stabilized at a lower pH when lactic acid is added (Corbion Purac 2013). Green olives, gherkins and other foods are often packed in a solution of salt, lactic acid and water. The lactic acid acts as a preservative by lowering the product's pH. The acidic environment controls the growth of spoilage microorganisms. It also improves the clarity of the brine by inhibiting spoilage and further fermentation. Lactic acid is responsible for the acid flavor, although it is a milder flavor as compared to acetic or citric acid. Similarly, a milder, more subtle taste is obtained when it is added to the vinegar in preparing certain pickles and relishes (Furia 1973). Due to its low pH, lactic acid is used to adjust the acidity and as a flavoring agent in the manufacture of cheese and dried food casein.

In dairy products such as cottage cheese, direct acidification with lactic acid is often preferred to fermentation as the risks of failure and microbial contamination can be avoided, and processing time is reduced. Lactic acid is used extensively in the production of Channa and Panneer (typically Indian foods) by direct acidification (Vijayakumar, Aravindan and Viruthagiri 2008). For direct acidification of certain breads, lactic acid is the natural sour dough acid. Because of its low pH, lactic acid can be added to dough to increase the shelf life due to its retarding action on molds and rope (*Bacillus subtilis* fermentation). When lactic acid is used in baking, it reacts with the baking soda (the baking soda neutralizes the acid), releasing carbon dioxide gas to assist in leavening the bread.

In cosmetic products, lactic acid is added for its moisturizing effect, which is related directly to lactate's water-retaining capacity. In addition, lactic acid creates a skin-lightening effect by suppressing the formation of tyrosinase and thereby reducing the production of melatonin (Vijayakumar, Aravindan and Viruthagiri 2008).

Sodium Lactate

Sodium lactate, when added to fresh meat, will delay the development of sour and off-flavors and is reported to be a very prominent flavor enhancer with few negative effects. One explanation for sodium lactate delaying the development of off-flavor is that it acts as a radical scavenger. It will bind to free radicals in meat to prevent lipid oxidation. Lipid oxidation is closely correlated to myoglobin oxidation. As lipid oxidation decreases, myoglobin oxidation decreases as well (McClure 2009). Under the USDA Food Safety and Inspection Service, these lactates are not allowed as flavoring agents in concentrations of more than 2% (USDA FSIS 2005).

Sodium lactate has been shown to improve cook yields of meat products because its humectant properties contribute to water-holding capacities of meat products. The increased processing yield with sodium lactate could also be due to a combination of increased levels of sodium ions and the humectants properties of sodium lactate (McClure 2009).

The addition of sodium lactate has been shown to increase the meat pH to produce a darker colored lean, the cut of the meat containing the least fat. The darker color meat containing sodium lactate also has been shown to stabilize with storage. This stabilization of meat color with storage is most likely due to the higher pH that provides some protection against oxidation during meat storage. Myoglobin is the pigment that gives meat its red color. When myoglobin is oxidized, it turns brown in the "metmyoglobin" state. Contributing factors for oxidation of myoglobin are pH, the amount of exposed light, microbial growth and time. At a higher pH, oxidation of myoglobin is not as rapid. As sodium lactate addition has been associated with increasing meat pH to increase water-holding capacity and reduce cook losses, the resulting meat is more tender (Miller 2010).

There are three proposed mechanisms by which sodium lactate can have an antimicrobial affect. The first is changing water activity (aw). The addition of sodium lactate lowers the water activity of the meat and thereby slows microbial growth. The second mechanism occurs as sodium lactate passes through the cell membrane and lowers intracellular pH, and the third takes place as sodium lactate affects cellular metabolism by inhibiting ATP[2] generation. The lactic acid portion of sodium lactate has antimicrobial properties, as it can be incorporated into the microbial cell. Lactic acid then interferes or slows down the normal metabolic process that generates energy in the cell. This metabolic process is called glycolysis. The sodium ion also has some antimicrobial effects (Miller 2010).

Potassium Lactate

Potassium lactate has a potassium ion rather than the sodium ion found in sodium lactate. Potassium lactate has been shown through research to improve meat color; improve juiciness and tenderness; enhance positive flavor attributes and decrease negative flavor attributes during storage; decrease microbial growth; and limit the growth of some major meat pathogens as previously discussed with sodium lactate. Potassium lactate can replace sodium lactate as a non-meat ingredient and has functionality similar to sodium lactate, but it does not have the off-flavor problems associated with sodium lactate such as higher salt taste, increased throat-burning mouth-feel, and higher levels of chemical aromatic flavor (Miller 2010).

<u>**Combinations of the Substance:**</u>

No additional ingredients (e.g., stabilizers, preservatives, carriers, anti-caking agents, or other materials) are generally added to commercially available forms of lactic acid, sodium lactate, or potassium lactate.

Lactic acid, sodium lactate and potassium lactate are commercially available as single ingredient materials. However, they may be combined with other ingredients for use in certain applications. For example, other

[2]ATP stands for adenosine triphosphate, a nucleoside triphosphate which transports chemical energy within cells for metabolism (Biology Online 2010)

ingredients can be combined with lactic acid to form buffered lactic acid, which contains calcium lactate and silicon dioxide. Calcium lactate is the calcium salt of lactic acid and is produced during lactic acid production. Silicon dioxide appears on the National List of Allowed and Prohibited Substances at 7 CFR Part 205.605(b) as "Permitted as a defoamer. Allowed for other uses when organic rice hulls are not commercially available" (USDA 2014).

Sodium lactate or potassium lactate may be combined with sodium diacetate. The reason for this is that low levels of sodium diacetate (i.e., below 0.2%) lower the pH of the surface of meat products and therefore decrease microbial growth. Research suggests that sodium diacetate in combination with other ingredients, such as sodium lactate or potassium lactate, is even more effective in retarding microbial growth and reducing the growth of some major foodborne pathogens, including *Listeria monocytogens*, than the addition of sodium diacetate to meat products alone. The antilisterial activity of sodium diacetate is not only due to the pH lowering effect, but to the activity of the acetate ion on listerial growth. Sodium diacetate is a GRAS substance and contains 60% sodium acetate and 40% acetic acid (Miller 2010).

There is no evidence to indicate that buffered lactic acid and sodium/potassium lactate-sodium diacetate combinations are harmful to humans or the environment.

Status

Historic Use:

Lactic Acid

Lactic acid was reviewed and recommended for listing on the National List by the NOSB in 1995 (Theuer 1995). It is currently listed at §205.605(a) of the National List of Allowed and Prohibited Substances under "Acids (Alginic; Citric—produced by microbial fermentation of carbohydrate substances; and Lactic)." Historical use in organic food processing is as a multipurpose food ingredient, as an antimicrobial agent, a curing and pickling agent, a flavoring agent, a pH control agent, and for other uses already described in this report.

Sodium Lactate and Potassium Lactate

Sodium lactate and potassium lactate were petitioned for inclusion on the National List of Allowed and Prohibited Substances, 7 CFR 205.605, on January 5, 2004. On January 22, 2004, the NOP notified the petitioner that the petitions were not necessary since the materials were combinations of materials already on the National List (i.e., lactic acid combined with sodium hydroxide and lactic acid combined with potassium hydroxide). Therefore, since the NOP's letter to the petitioner was released, both sodium lactate and potassium lactate have been allowed for use in organic processing. It is not clear whether certifiers have allowed it for all applications or just for meat production.

On June 25, 2014, the NOP issued a memorandum to the National Organic Standards Board (NOSB) regarding the regulatory statuses of sodium lactate and potassium lactate. In that memorandum, the NOP acknowledged that the interpretation published on January 22, 2004, was not consistent with previous NOSB recommendations on classification of materials, and they requested that the NOSB take up the petitions for these two substances for consideration for inclusion on the National List (McEvoy 2014).

Organic Foods Production Act, USDA Final Rule:

Lactic Acid

Lactic acid does not appear specifically in OFPA. It is permitted as a nonagricultural (nonorganic) substance allowed as an ingredient in or on processed products labels as "organic" or "made with organic (specified ingredients of food group(s))" per 7 CFR Part 205.605(a) as "Acids (Alginic; Citric—produced by microbial fermentation of carbohydrate substances; and Lactic)" (USDA 2014).

Sodium Lactate and Potassium Lactate

Sodium lactate and potassium lactate do not appear in OFPA. They are not listed on the National List of Allowed and Prohibited Substances 7 CFR Part 205.605. They are only permitted for use in organic processing by way of a 2004 notification from the USDA to the petitioner of sodium and potassium lactate.

However, the individual materials combined to produce both sodium lactate (e.g., lactic acid and sodium hydroxide) and potassium lactate (e.g., lactic acid and potassium hydroxide) are included at 7 CFR Part 205.605. Sodium hydroxide and potassium hydroxide are allowed synthetic materials. Sodium hydroxide was reviewed and recommended for listing on the National List by the NOSB in 1995. Potassium hydroxide was recommended for listing on the National List by the NOSB in 2001.

International

Lactic acid is currently permitted under all four of the most prevalent organic standards (U.S., EU, Canada, JAS) for various uses and with various provisions as outlined below.

Sodium lactate and potassium lactate are not permitted under the standards listed below.

Canada - Canadian General Standards Board Permitted Substances List

Lactic acid is allowed for use in processed organic products per CAN/CGSB 32.311 Table 6.3 Non-organic Ingredients Classified as Food Additives as follows: "For fermented vegetable products or in sausage casings."

Sodium lactate and potassium lactate are not listed for use in processing. However, sodium hydroxide is allowed for use in processing and is listed at CAN/CGSB 32.311 Table 6.3 Non-organic Ingredients Classified as Food Additives without restriction, and at Table 6.6 Processing Aids as follows: "Prohibited for use in lye peeling of fruits and vegetables." Potassium hydroxide is allowed for use in processing and is listed at CAN/CGSB 32.311 Table 6.6 Processing Aids as follows: "For pH adjustment only. Prohibited for use in lye peeling of fruits and vegetables."

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)

Lactic acid is permitted by the CODEX Alimentarius per Table 3, Ingredients of Non-Agricultural Origin Referred to in Section 3 of These Guidelines, as follows: Lactic Acid (L- D- and DL-) is allowed in "**Food of Plant Origin**: 04.2.2.7 Fermented vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes and aloe vera), and seaweed products, excluding fermented soybean products, of food category 12.10." Lactic acid is also allowed in "**Food of Animal Origin:** 01.0 Dairy products and analogues, excluding products of food category 02.0. 08.4, and Edible casings (e.g. sausage casings)."

Sodium lactate and potassium lactate are not listed for use in processing. However, sodium hydroxide is allowed for use in processing and is listed Table 3 Ingredients of Non-Agricultural Origin Referred to in Section 3 of These Guidelines as follows: "permitted for **Food of Plant Origin**: 06.0 Cereals and cereal products, derived from cereal grains, from roots and tubers, pulses and legumes, excluding bakery wares of food category 07.0. 07 .1.1.1 yeast-leavened breads and specialty breads." Sodium hydroxide is not allowed in food of animal origin under CODEX. Sodium hydroxide is also listed at Table 4 Processing Aids Which May Be Used For The Preparation of Products of Agricultural Origin Referred to in Section 3 of these Guidelines as follows: "pH adjustment in sugar production."

Potassium hydroxide is allowed for use in processing and is listed at Table 4 Processing Aids Which May Be Used For The Preparation of Products of Agricultural Origin Referred to in Section 3 of these Guidelines as follows: "pH adjustment in sugar production."

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008

In Annex VIII A Food Additives, Including Carriers, lactic acid is allowed in processing foodstuffs of both plant and animal origin without any specific conditions. Under Annex VIII D Processing Aids for the Production of Yeast and Yeast Products, lactic acid is also allowed as follows "For the regulation of pH in yeast production."

Under Annex VIII A Food Additives, Including Carriers, Sodium lactate is allowed for use in processing foodstuffs of animal origin only and is listed as follows: "Milk-based and meat products."

Potassium lactate is not listed as permitted in processing. Similarly, potassium hydroxide is also not listed as permitted in processing.

Japan Agricultural Standard (JAS) for Organic Production
Lactic acid is included in JAS Notification No. 1606 of the Ministry of Agriculture, Forest and Fisheries, of October 27, 2005, revised 2012:Table 1 – Additives as follows: "Limited to be used for processed vegetable or rice products, for sausage as casing, for dairy products as coagulating agent, and for cheese in salting as pH adjuster."

Sodium lactate and potassium lactate are not listed in the JAS standard and therefore are not permitted.

Sodium hydroxide is listed on Table 1 as follows: "Limited to be used for processing sugar as pH adjustment agent or used for grain processed foods."

Potassium hydroxide is listed on Table 1 as follows: "Limited to be used for processing sugar as pH adjustment agent."

International Federation of Organic Agriculture Movements (IFOAM)
Lactic acid is permitted for use under IFOAM Norms for Organic Production and Processing, 2014. It appears in Appendix 4 – Table 1: List of Approved Additives and Processing/Post-harvest Handling Aids. There are no limitations on use.

Sodium and potassium lactates are not specifically listed on any of the appendices in the IFOAM Norms/Standards.

Sodium hydroxide is allowed in Appendix 4 - Table 1: List of Approved Additives and Processing/Post-harvest Handling Aid as follows: "Sugar processing and the treatment of surfaces for traditional bakery products."

Potassium hydroxide is not permitted for organic processing under the IFOAM Norms/Standards.

Evaluation Questions for Substances to be used in Organic Handling

<u>Evaluation Question #1:</u> Describe the most prevalent processes used to manufacture or formulate the petitioned substance. Further, describe any chemical change that may occur during manufacture or formulation of the petitioned substance when this substance is extracted from naturally occurring plant, animal, or mineral sources (7 U.S.C. § 6502 (21)).

Lactic Acid
To produce nonsynthetic lactic acid commercially, the most common manufacturing process is via carbohydrate fermentation using homolactic organisms such *as Lactobacillus delbrueckii, L. bulgaricus*, and *L. leichmanii*. A wide variety of carbohydrate sources, e.g., molasses, corn syrup, whey, dextrose, and cane or beet sugar, can be used. Proteinaceous and other complex nutrients required by the organisms are provided by corn steep liquor, yeast extract, soy hydrolysate, etc. If starch is used, the starch needs to be enzymatically hydrolyzed prior to fermentation. Production of lactic acid from starch materials requires a pretreatment process for gelatinization and liquefication, which is carried out at a temperature between 90 and 130°C for 15 min, followed by enzymatic saccharification to glucose (enzymatic hydrolysis), followed by conversion of glucose to lactic acid by fermentation (Zhang, Jin and Kelly 2007).

During the fermentation process, the pH is kept at a constant value by the addition of lime (calcium carbonate), which neutralizes the acid and results in the formation of calcium lactate, a calcium salt of the acid, in the broth. The fermentation is conducted batchwise, taking 4-6 days to complete, and lactate yields of approximately 90 wt% from a dextrose equivalent of carbohydrate are obtained.

For the purification process, after fermentation has ended, the calcium lactate-containing broth is generally heated to 70°C to kill the bacteria, filtered to remove cells, carbon-treated, evaporated, and acidified with sulfuric acid to pH 1.8 to convert the calcium lactate salt into lactic acid. The by-product, insoluble calcium sulfate (gypsum), is removed by filtration. The filtrate is further purified by carbon columns and ion exchange and evaporated to produce technical-grade and food-grade lactic acid (HSDB® 2006).

Vijayakumar, Aravindan, and Viruthagiri (2008) identify the various different ways in which lactic acid can be recovered and purified:

1. The heated and filtered fermentation broth is concentrated to allow crystallization of calcium lactate, followed by addition of sulfuric acid to remove the calcium as calcium sulfate. The lactic acid is then re-crystallized as calcium lactate, and activated carbon is used to remove colored impurities.
2. An alternative to the latter step, the zinc salts of lactic acid are sometimes prepared because of the relatively lower solubility of zinc lactate. In another procedure, the free lactic acid is solvent extracted with isopropyl ether directly from the heated and filtered fermentation broth. This is a counter current continuous extraction, and the lactic acid is recovered from the isopropyl ether by further counter-current washing of the solvent with water.
3. The methyl ester of the free lactic acid is prepared, and this is separated from the fermentation broth by distillation followed by hydrolysis of the ester by boiling in dilute water solution (the methyl ester decomposes in water). The lactic acid is then obtained from the aqueous solution by evaporation of the water, and the methanol is recovered by distillation.
4. Secondary or tertiary alkyl amine salts of lactic acid are formed and then extracted from aqueous solution with organic solvents; the solvent is removed by evaporation, and the salt then is decomposed to yield the free acid.
5. An older procedure, not utilized commercially to any extent today, involves direct high-vacuum steam distillation of the lactic acid from the fermentation broth, but decomposition of some of the lactic acid occurs (Vijayakumar, Aravindan and Viruthagiri 2008).

The Organic Materials Review Institute (OMRI) has also identified an alternative process where ethanol is added to the refined material, which reacts with the lactic acid to make ethyl lactate. The ester is purified (separated) by distillation and then hydrolyzed into ethanol and lactic acid. Ethanol is evaporated out to complete concentration of lactic acid (OMRI 2014a).

Alternate lactic acid production, which is not yet commonly employed because it is still being researched, can occur using various fungal species of the *Rhizopus* genus. Zhang, Jin, & Kelly (2007) review recent research in process engineering, metabolic and enzymatic mechanisms, and molecular technologies associated with lactic acid production by the *Rhizopus* fungi.

In this system, the glucose is the preferred carbon source for L-lactic acid production by *Rhizopus* species, followed by starch material. In contrast to the processing described above, simultaneous saccharification and fermentation (SSF) integrates the saccharification and fermentation steps (Zhang, Jin and Kelly 2007).

Sodium Lactate

Sodium lactate is produced by combining lactic acid with sodium hydroxide, which are both substances appearing in section 205.605 of the National List.

Alternative Production of Sodium Lactate

According to China Petroleum and Chemical Corporation (2013), conventional sodium lactate can be produced by reacting lactic acid and sodium carbonate or sodium hydroxide. Sodium carbonate is also listed at 7 CFR Part 205.605(a), with no restrictions on use. Lactates can be purified through concentration, ion exchange filtration, and bleaching with a vegetable carbon.

Another alternative procedure for preparing sodium lactate without the use of sodium hydroxide consists briefly of the following steps: First the traditional fermentation process to produce lactic acid is employed, but the killing step is carried out at a temp of 180°F with sufficient lime added. The resulting calcium lactate liquor is then separated by filtration from the insoluble matter present. The calcium lactate liquor at this stage usually has a dark, reddish brown color, which can be partly reduced by bleaching with a vegetable carbon. Either the bleached or unbleached liquor is then converted to sodium lactate by reacting the liquor with sodium carbonate, forming the insoluble salt, calcium carbonate. The insoluble calcium carbonate is separated from the alkaline sodium lactate liquor by filtering and the pH of the filtered sodium lactate is then adjusted to the proper value by adding a suitable acid. The sodium lactate without further chemical treatment is concentrated to the desired concentration, usually 50% sodium lactate. Prior to the concentration step or after a partial concentration, bleaching of the sodium lactate solution with vegetable carbon is often used (Morgan and Goodman 1939).

Potassium Lactate

Potassium lactate is produced by combining lactic acid with potassium hydroxide, which are both substances appearing in section 205.605 of the National List.

Potassium lactate is used for low-sodium applications and is produced similarly to sodium lactate (Jungbunzlauer Suisse Ag 2014). No other ingredients or additives are added to the final product however, as in the case with sodium lactate, potassium lactate can be purified through concentration, ion exchange filtration, and bleaching with a vegetable carbon (Plunk Biochemical Company 2014).

<u>Evaluation Question #2:</u>**Discuss whether the petitioned substance is formulated or manufactured by a chemical process, or created by naturally occurring biological processes (7 U.S.C. § 6502 (21)). Discuss whether the petitioned substance is derived from an agricultural source.**

Lactic Acid

Lactic acid is derived from an agricultural source that is fermented by non-pathogenic and non-toxic bacteria. Fermentation processes such as these are considered naturally occurring biological processes. During the purification process to produce the food-grade product, calcium carbonate, sulfuric acid, and activated carbon are used to chemically convert lactic acid to lactate salts, and then back to lactic acid. These purification steps chemically change lactic acid, but it is eventually converted back to the original chemical as found in nature and in the fermentation broth.

Lactic acid is produced by humans, animals, plants and microorganisms. It is the simplest hydroxyl carboxylic acid with an asymmetrical carbon atom. Lactic acid is produced from agricultural raw materials. Industrial scale batch fermentation by homofermentative lactic acid bacteria uses defined substrates such as sucrose (originating from cane or beet sugar) or dextrose (originating from corn) along with whey, molasses, starch waste, beets and other carbohydrate-rich materials). Starches are often hydrolyzed with enzymes to form glucose prior to fermentation.

While raw materials like corn and beet sugar used to produce sucrose or dextrose may be sourced from a large supply pool, including genetically modified sources, the combination of processing of raw materials into dextrose and sucrose, use of non-GMO microorganisms to produce lactic acid, and the refining and purification processes involved would remove any traces of GMO DNA from the final product.

For the recovery of lactic acid, additional calcium carbonate is added to the medium, the pH is adjusted to approximately 10, and the fermentation broth is heated and then filtered. This procedure chemically converts all of the lactic acid to calcium lactate, kills bacteria, coagulates protein of the medium, removes excess calcium carbonate, and helps to decompose any residual sugar in the medium. Calcium carbonate is an approved nonsynthetic material on 7 CFR Part 205.605(a) of the National List.

Various processes are employed for the recovery and purification of the lactic acid. In one procedure, the heated and filtered fermentation broth is concentrated to allow crystallization of calcium lactate, and sulfuric acid is added to react with the calcium lactate, remove the calcium as calcium sulfate and reconvert the lactate to lactic acid (Zhang, Jin and Kelly 2007).

Activated carbon (also known as activated charcoal) is currently listed on section 205.605(b) on the National List. It is used as a filtration agent to physically remove colored impurities during lactic acid production.

Sodium Lactate and Potassium Lactate

Sodium lactate is produced through a chemical process. Lactic acid is reacted with sodium hydroxide, which forms the sodium salt of lactic acid, sodium lactate. Adding sodium hydroxide, which is an alkali material, neutralizes the lactic acid to form the sodium salt (Houtsma 1996).

Potassium lactate, the potassium salt of lactic acid, is produced the same way as sodium lactate, except that potassium hydroxide replaces sodium hydroxide.

These are chemical reactions that result in substances that are chemically distinct from nonsynthetic lactic acid.

<u>Evaluation Question #3:</u> **If the substance is a synthetic substance, provide a list of nonsynthetic or natural source(s) of the petitioned substance (7 CFR § 205.600 (b) (1)).**

Lactic acid

Lactic acid, produced from fermentation, is currently listed on the National List, 205.605(a) as a nonsynthetic material with no restrictions on use. Other organic acids appearing on 7 CFR 205.605(a), including citric acid, malic acid, and tartaric acid, can be used in place of lactic acid as acidulants and flavor enhancers. Certain bacteria, such as *Lactobacillu*s and *Streptococcus*, naturally produce lactic acid. These bacteria can naturally occur in, and/or be added during the manufacturing processes of foods like yogurt, pickled vegetables, sourdough bread, beer and wine. For example, in yogurt, the bacteria produce lactic acid during the fermentation of lactose. (Kenneth Todar 2012). Lactic acid lowers the pH of the product, causes the milk proteins to thicken, and gives yogurt its tart taste (Vijayakumar, Aravindan and Viruthagiri 2008). It acts as a flavoring and a preserving agent (Jungbunzlauer Suisse Ag 2012).

Sodium Lactate and Potassium Lactate

Sodium lactate and potassium lactate are produced by combining nonsynthetic lactic acid and sodium hydroxide or potassium hydroxide, respectively. The reaction between the lactic acid and the hydroxide is a synthetic reaction. There does not appear from the literature to be a nonsynthetic version of sodium lactate or potassium lactate.

<u>Evaluation Question #4:</u> **Specify whether the petitioned substance is categorized as generally recognized as safe (GRAS) when used according to FDA's good manufacturing practices (7 CFR § 205.600 (b)(5)). If not categorized as GRAS, describe the regulatory status.**

Lactic Acid

Lactic acid is established as GRAS at 21 CFR 184.1061. Its GRAS listing is based upon the following current good manufacturing practice conditions of use:

1. The ingredient is used as an antimicrobial agent as defined in 21 CFR 170.3(o)(2);
2. as a curing and pickling agent as defined in 21 CFR 170.3(o)(5);
3. as a flavor enhancer as defined in 21 CFR 170.3(o)(11);
4. as a flavoring agent and adjuvant as defined in 21 CFR 170.3(o)(12);
5. as a pH control agent as defined in 21 CFR 170.3(o)(23); and
6. as a solvent and vehicle as defined in 21 CFR 170.3(o)(27).
7. The ingredient is used in food, except in infant foods and infant formulas, at levels not to exceed current good manufacturing practice.

(Food and Drug Administration 1984)

Sodium Lactate

Sodium lactate is affirmed as GRAS at 21 CFR 184.1768.The GRAS affirmation as a direct human food ingredient is based upon the good manufacturing practice conditions of use:

1. The ingredient is used as an emulsifier as defined in 21 CFR 170.3(o)(8);
2. as a flavor enhancer as defined in 21 CFR 170.3(o)(11);
3. as a flavoring agent or adjuvant as defined in 21 CFR 170.3(o)(12);
4. as a humectant as defined in 21 CFR 170.3(o)(16); and

5. as a pH control agent as defined in 21 CFR 170.3(o)(23).

(Food and Drug Administration 2008)

Potassium Lactate

Potassium lactate is affirmed as GRAS at 21 CFR 184.1639.The affirmation of this ingredient as GRAS as a direct human food ingredient is based upon the good manufacturing practice conditions of use:

1. The ingredient is used as an emulsifier as defined in 21 CFR 170.3(o)(8);
2. as flavor enhancer as defined in 21 CFR 170.3(o)(11);
3. as flavoring agent or adjuvant as defined in 21 CFR 170.3(o)(12);
4. as humectant as defined in 21 CFR 170.3(o)(16); and
5. as pH control agent as defined in 21 CFR 170.3(o)(23).

(Food and Drug Administration 2008)

<u>Evaluation Question #5:</u> Describe whether the primary technical function or purpose of the petitioned substance is a preservative. If so, provide a detailed description of its mechanism as a preservative (7 CFR § 205.600 (b)(4)).

A chemical food preservative is defined under FDA regulations at 21 CFR 101.22(a) (5) as "any chemical that, when added to food, tends to prevent or retard deterioration thereof, but does not include common salt, sugars, vinegars, spices, or oils extracted from spices, substances added to food by direct exposure thereof to wood smoke, or chemicals applied for their insecticidal or herbicidal properties" (FDA 2013).

Lactic Acid

Lactic acid is one of the most widely distributed acids and preservatives in nature (McClure 2009). As described above, its uses in food are vast and varied. Lactic acid's antimicrobial action is based mainly on its ability to reduce the pH of the aqueous phase of the food, inhibit enzymes, and inhibit the nutrient transport and overall impact on metabolic activity of pathogenic microorganisms (Campos, et al. 2011).

Sodium Lactate and Potassium Lactate

One of the primary uses of sodium lactate and potassium lactate is as a preservative in meat. As stated above, sodium (and potassium) lactate has the ability to extend shelf-life of meat products. The proposed mechanisms by which it functions as a preservative are discussed above under *Action of the Substance*.

<u>The USDA Food Standards and Labeling Policy Book:</u>

It should be noted that meat products that contain sodium and potassium lactates can no longer be labeled as "natural" without a case-by-case assessment of what function these materials are serving in the product, and at what levels (USDA FSIS 2005). The reason is that the lactates are likely to be used as "chemical preservatives," rather than as flavors. However, this brings up the issue of dual-function ingredients, whereby the ingredient may be considered as a natural ingredient for flavor and/or function, but can also have a dual function as a "natural" preservative. The issue of "natural preservative" vs. "chemical preservative" has not been formally defined. According to the USDA FSIS, any "preservative" used in a HACCP program that allows a processor to classify their product in Alternative 1 or Alternative 2, in regard to *Listeria monocytogenes* control, would not be permitted to be labeled as "natural" (Sebranek 2007). Refer to Evaluation Question #11 for more information on the Listeria Rule and the use of preservatives such as sodium and potassium lactate.

The USDA Food Standards and Labeling Policy Book was revised in August 2005 to clarify that, since sodium lactate and potassium lactate are ingredients known to have multiple technical effects on meat products in which they are used, including antimicrobial effects, the use of these materials will be judged on a case-by-case basis at the time of label approval by the FSIS. If these materials serve as antimicrobials in the meat products, they cannot make "natural claims."The Policy Book specifically states that:

> "… information indicates that sodium lactate, potassium lactate, and calcium lactate provide an antimicrobial effect at levels that have been regulated as providing a flavoring effect. Therefore,

> regardless of whether it can be shown that any form of lactate is from a natural source and is not more than minimally processed, the use of lactate (sodium, potassium, and calcium) may conflict with the meaning of "natural" because it may be having a preservative effect at levels of use associated with flavoring. Thus, listing "sodium lactate (from a corn source)" in the previous entry may have been in error, at least without qualifying the listing by stating that the use of this ingredient or any ingredient known to have multiple technical effects needs to be judged on a case-by-case basis at the time of label approval to assess that the intended use, level of use, and technical function are consistent with the 1982 policy.… Therefore, FSIS has removed the reference to sodium lactate from this guidance but will judge claims that foods to which a lactate has been added can be characterized as "natural" on a case-by-case basis, pending the outcome of a rulemaking on the use of "natural" that the Agency intends to initiate in the near future." (USDA FSIS 2005)

<u>Evaluation Question #6:</u> Describe whether the petitioned substance will be used primarily to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law) and how the substance recreates or improves any of these food/feed characteristics (7 CFR § 205.600 (b)(4)).

Lactic Acid

While lactic acid is not used to recreate or replace flavors, colors, textures, or nutritive values lost during processing, its major functions are as a flavor or flavor enhancer, and to assist with texture and stability in certain food products. As stated previously, lactic acid is used to produce a mild and pleasant taste in acid pickles, relishes and salad dressings; improve the taste and flavor of many beverages, such as soft drinks, mineral water, carbonated fruit juices; improve the microbial stability as well as flavor in large-scale beer manufacturing; and improve the taste and flavors in the processing of meal in sauces for canned fish, by masking the amine flavors from fish meal (Vaishnavi Bio-Tech Limited 2011).

Sodium Lactate and Potassium Lactate

Similar to lactic acid, sodium and potassium lactates do not recreate or replace flavors, colors, textures, or nutritive values lost in processing, but are often used to improve or enhance flavors and textures of food products, especially meat. Sodium lactate is known to enhance meat flavor due to the salty taste that it provides, while assisting with color retention and water holding capacity (McClure 2009). Houtsma (1996) reported that an increase in sodium lactate levels from 0% to 4% in cooked beef roasts was found to result in a darker red color with less gray surface, and improved juiciness and tenderness of the meat product. Potassium lactate offers similar attributes but is less salty, appealing to low-sodium applications. McClure (2009) explains that when added to fresh meat, these lactates will delay the development of sour and off-flavors. And for precooked products such as roasts, adding sodium lactate enhances flavor notes, resulting in a stronger beefy flavor. Addition of sodium lactate results in enhancement of overall flavor and beef flavor intensity. By adding sodium lactate to a meat product, the amount of salt (NaCI) could be decreased while still maintaining the desired level of salt flavor.

<u>Evaluation Question #7</u>*:* Describe any effect or potential effect on the nutritional quality of the food or feed when the petitioned substance is used (7 CFR § 205.600 (b)(3)).

Lactic Acid

There is research to support the theory that the addition of lactic acid to unfermented maize products, such as tortillas, significantly improves iron bioavailability without affecting the organoleptic characteristics of these products (Proulx 2007).

The nutritional benefits of lactic acid fermented foods are well documented. Research suggests that lactic acid fermentation enhances the micronutrient profile of several foods such as yogurt, kefir, fermented vegetables, fruit, legumes and grains. This is said to be caused by the increased bioavailability of amino acids in these foods, particularly lysine and methionine. Vegetables that have undergone lactic acid fermentation, such as sauerkraut and kimchi, often see an increase in Vitamin C and Vitamin A activity. In fermented grains, lactic acid fermentation reduces the naturally occurring phytic acid content, which makes the grains easier to digest and the minerals easier to absorb (Nourished Kitchen 2009).

Sodium and Potassium Lactate

Neither sodium nor potassium lactates appear to be added to foods to increase nutrient availability, or to enrich or fortify foods. They are added as flavoring agents or enhancers, as humectants (which help foods retain water and retain moisture longer), and to maintain acid levels in foods (Livestrong 2013). However, sodium lactate injections can be administered to individuals for fluid and electrolyte replenishment, as an alkalinizing agent, and for a boost of calories. The pH is sometimes adjusted with lactic acid (Drugs.com 2014).

Evaluation Question #8: List any reported residues of heavy metals or other contaminants in excess of FDA tolerances that are present or have been reported in the petitioned substance(7 CFR § 205.600 (b)(5)).

The Joint Expert Committee on Food Additives Monograph (2004) reports a lead level of not more than 2 mg/kg for lactic acid. The Joint Expert Committee on Food Additives Monograph (2003) reports a lead level of not more than 2 mg/kg for both sodium lactate and potassium lactate. A review of several MSDS and technical sheets for lactic acid, sodium lactate, and potassium lactate indicated no presence of heavy metals or other contaminants in excess of FDA tolerances.

Evaluation Question #9: Discuss and summarize findings on whether the manufacture and use of the petitioned substance may be harmful to the environment or biodiversity (7 U.S.C. § 6517 (c) (1) (A) (i) and 7 U.S.C. § 6517 (c) (2) (A) (i)).

The EPA Screening-Level Hazard Characterization of High Production Volume Chemicals report for Lactic Acid and its salts (2008) concluded that the manufacture and use of natural lactic acid constitutes a low potential risk to human health or the environment. According to the data assessed in the report, lactic acid and salts are readily biodegradable and have low potential to persist in the environment. Further, the potential acute hazard of lactic acid to aquatic organisms is low (Environmental Protection Agency 2008).

According to Pal (2012), the conventional fermentation based processes, which are batch processes with poor productivity, require a number of downstream processing steps that involve high energy, equipment, and time and labor costs as well as harsh chemical use. Because the conventional process, which relies on the addition of alkalis, produces salts of lactic acid first instead of direct lactic acid and involves an additional 50% cost due to chemicals as well as additional separation and purification steps, this process results in large quantities of calcium sulfate as a solid waste (Pal 2012). Calcium sulfate, or gypsum, is produced through the addition of calcium carbonate and sulfuric acid in the lactic acid manufacturing process. It is a by-product in the process and is produced at a rate of 1 ton per 1 ton of lactic acid produced (Pal 2012). Gypsum disposal can be a problem.

Pal (2012) looked at process intensification measures that utilize continuous fermentation processes with membrane cell recycling systems, which increases mass transfer rate, productivity, and efficient separation of lactic acid from by-products (unconverted sugars and other impurities) to achieve a desired product. This technology is also said to be environmentally benign (Pal 2012). The use of nanofiltration is also a part of this process intensification system.

One of the main commercial lactic acid manufacturers, Archer Daniels Midland Company (ADM), has partnered with a fertilizer company to sell and distribute much of the gypsum by-product to growers (Gypsoil and ADM 2011).

Corbion (Purac), another large commercial lactic acid manufacturer, indicates on their website that the by-products produced include agricultural debris, unconverted sugars and filtered microbes (used as organic fertilizer), gypsum (used for plasterboard), and distillation residue (used for animal feed). However, the company acknowledges that the amount of gypsum being produced because of the lactic acid and poly lactic acid processes has reached unsustainable levels. The company is investing in the development of a proprietary gypsum-free technology that does not rely on the use of calcium carbonate or sulfuric acid in the acidification and purification processes. This technology appears to be in the initial stages of development, and more information on the details of this technology is needed. According to Corbion, this technology will rely on fewer chemicals, reduce the environmental load, and lessen the carbon footprint of the lactic acid manufacturing process (Corbion 2014).

<u>Evaluation Question #10:</u> Describe and summarize any reported effects upon human health from use of the petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (i), 7 U.S.C. § 6517 (c) (2) (A) (i)) and 7 U.S.C. § 6518 (m) (4)).

The EPA Screening-Level Hazard Characterization of High Production Volume Chemicals report for Lactic Acid and its salts (2008) concluded that the manufacture and use of natural lactic acid poses a low potential risk to human health (Environmental Protection Agency 2008).

Lactates have been reported to have low oral toxicity, with a lack of adverse effects in feeding studies in which up to 3,900 mg/kg body weight/day was administered to rats for 2 years. Likewise, lactates were proven to be non-genotoxic and non-mutagenic (Purac 2008).

In reviewing the safety of lactic acid and its sodium, potassium, and calcium salts, the Joint FAO/WHO Expert Committee on Food Additives (JECFA, 1974) concluded that it was "unnecessary to set ADI limits" for these additives since lactic acid is a normal constituent of food and a normal intermediary metabolite in humans. In another review of the safety of lactic acid and calcium lactate conducted by the Federation of American Societies for Experimental Biology (FASEB, 1978) for the FDA, similar conclusions were drawn by the Select Committee indicating that lactic acid and calcium lactate were safe for use by "individuals beyond infancy when they are used at levels that are now current or that might reasonably be expected in the future" (Purac 2008).

As described in other sections of this report, the use of lactic acid and its sodium and potassium salts in certain food applications may reduce the risk of foodborne pathogens because of their antimicrobial properties.

<u>Evaluation Question #11:</u> Describe any alternative practices that would make the use of the petitioned substance unnecessary (7 U.S.C. § 6518 (m)(6)).

Lactic Acid

As discussed previously, lactic acid is produced naturally in many foods by lactic acid bacteria. Lactic acid bacteria are approved for use in organic processing under the listing for microorganisms at 7 CFR Part 205.605(a).

Commercially manufactured lactic acid is a nonsynthetic chemical widely used in the food industry. It is used in a variety of ways that may not easily be substituted by alternative practices, including acidification, as a flavor, and as an antimicrobial agent. For example, although lactic acid can be produced *in situ* by lactic acid bacteria, commercially manufactured lactic acid is often used in place of fermentation (e.g., in cottage cheese production) in order to avoid risks of failure and contamination (Vijayakumar, Aravindan and Viruthagiri 2008).

Sodium Lactate and Potassium Lactate

The petitioner of these two substances stressed the importance of using these materials to control *Listeria monocytogenes* (Lm), especially in light of the Listeria Rule guideline released by the USDA Food Safety and Inspection Service (FSIS), which codified the regulations that establishments are required to follow to produce safe Ready-To-Eat (RTE) product (USDA FSIS 2012). The Listeria Rule offers several alternatives to manufacturers of RTE products:

1. The establishment applies a post-lethality treatment to reduce or eliminate Lm and an antimicrobial agent or process to suppress or limit growth of Lm. Sodium and potassium lactate could be used as antimicrobial agents under this alternative. Examples of products that would fall under this alternative would be deli and hotdog products that are steam pasteurized after packaging and have lactates added in the formulation.

2. The establishment applies either a post-lethality treatment or an antimicrobial agent or antimicrobial process. Under this alternative, sodium and potassium lactate could be used or the post-lethality treatment or the antimicrobial process. An example of a product that would fall under this alternative is a hotdog or deli product that is treated with a post pasteurization treatment after packaging, such as a steam treatment, and does not contain lactates or any antimicrobial agents.
3. The establishment does not apply any of the options above and instead relies on its sanitation program to control Lm. Ongoing and more frequent verification testing of food contact surfaces in the post-lethality processing area to ensure that surfaces are sanitary and free of Lm or its indicator organisms is required. FSIS also carries out more frequent testing of products that are produced under this alternative. An example is refrigerated chicken nuggets that are not treated with a post lethality treatment or antimicrobials. Additional verification testing requirements for establishments that produced deli or hotdog products are enforced.

(USDA FSIS 2012)

While the first alternative is the most conservative approach, the Listeria Rule only applies to products that are RTE and exposed to the environment after the lethality step (which is defined as cooking or another process such as fermentation or drying that results in a product that is safe for consumption without further preparation) (USDA FSIS 2012).

"Antimicrobial process" is defined in the Listeria Rule as freezing in order to suppress or limit the growth of a microorganism, such as Lm, throughout the shelf life of the product. Other examples include processes that result in a pH or water activity that suppresses or limits microbial growth.

Processing alternatives include cook-in-bag products, frozen products with safe handling instructions for cooking, strict facility sanitation and testing requirements (under the FSIS's Listeria Rule (USDA FSIS 2012)), or post processing applications such as high pressure pasteurization and steam/water pasteurization. While it appears that alternative practices do exist that would make the use of sodium and potassium lactates nonessential, each establishment has products and processes that require specific approaches to control of microorganism contamination. Establishments may even need to utilize multiple alternatives depending on the types of products, facilities, and resources available (USDA FSIS 2012).

Evaluation Question #12: Describe all natural (non-synthetic) substances or products which may be used in place of a petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (ii)). Provide a list of allowed substances that may be used in place of the petitioned substance (7 U.S.C. § 6518 (m) (6)).

Lactic Acid

Lactic acid is listed at 7 CFR Part 205.605 (a) as an approved nonsynthetic material for use in products labeled as "organic" or "made with organic (specified ingredients of food group(s))." As stated above, other organic acids appearing on 7 CFR 205.605(a), including citric acid, malic acid, and tartaric acid, can be used in place of lactic acid as acidulants and flavor enhancers.

Sodium Lactate and Potassium Lactate

Sodium and Potassium Lactates are mainly used as preservatives in meat products due to food safety concerns. Processed nonorganic meat products such as hams, bacon, frankfurters, bologna, and others are commonly cured by addition of sodium nitrite and sometimes sodium nitrate, both of which are prohibited in organic products. Sodium nitrate is a mined mineral sourced primarily from Chile and Peru (ICF International 2011) but can also be produced synthetically by neutralizing nitric acid with sodium carbonate or sodium hydroxide (PubChem Open Chemistry Database 2014). Sodium nitrite is produced from sodium nitrate through the use of heat, light, ionizing radiation and a metal catalyst (PubChem Open Chemistry Database 2014). Both nitrates and nitrites are permitted in the U.S. to be used in curing nonorganic meat and poultry with the exception of bacon, where nitrate use is prohibited. Sodium nitrite is commonly used in the U.S. and around the world (Meats and Sausages 2014). In these processed meat products, sodium and potassium lactate can serve as alternatives to the nitrates and nitrites, which have been associated with nitrosamine formation in cured meats. Nitrates and nitrites are also prohibited for use in meats labeled as "natural" (Sebranek 2007). There is concern that organic meat products could potentially pose a food safety hazard if they do not contain antimicrobials that are comparable to formulated sodium nitrite ($NaNO_2$) in concentrations known to be highly effective in inhibiting the growth of many food borne pathogens such as *Listeria monocytogenes* (Niebuhr, et al. 2010). However, more research (as discussed below) into natural antimicrobials in organic and natural meat products is being done with promising results.

According Niebuhr, et al. (2010), natural antimicrobials often need to be combined or used at higher levels in order to control pathogens, which can have negative impacts on sensory characteristics (color, flavor, aroma). Alternative nonsynthetic additives include vegetable and fruit juice powders that contain natural nitrite, or that modify pH. Other nonsynthetic alternatives include organic acids such as citric and lactic acid, lactic acid starter cultures such as *Staphylococcus carnosus*, vinegar, essential oils and bacteriophages.

Vinegar, essential oils, and vegetable and fruit juice powders are natural, but they are also agricultural. Therefore, antimicrobials containing these ingredients will be discussed in Question #13 below.

Research into natural antimicrobials for the control of pathogens such as *Listeria monocytogenes* in foods is ongoing. The ability of *L. monocytogenes* to survive a wide range of adverse conditions, including acidic pH, low temperatures, and high sodium chloride concentrations make the organism difficult to control in food. Several studies that utilize various preservation techniques for the control of Listeria in foods are being conducted. Most of them aim at achieving food safety without compromising the sensory and nutritional qualities of foods (Campos, et al. 2011).

<u>Organic Acids</u>:
Campos, et al. (2011) looked at the effectiveness of organic acids in controlling *L. monocytogenes*. The results of these studies were promising; however, in many instances, combinations of additives or preservative treatments worked best because the efficacy of the antimicrobials can be influenced by the chemical composition and the physical conditions of the various foods.

The organic acids include acetic, lactic, malic and citric acid. The antimicrobial action of organic acids is based mainly on their ability to reduce the pH of the aqueous phase of the food. In the cases of weak lipophilic organic acids such as acetic or sorbic acid, the undissociated form is also able to penetrate the cell membrane. The latter exerts its inhibitory action by dissociating and acidifying the cytoplasm. Additionally, other mechanisms take place such as inhibition of enzymes, nutrient transport and overall reduction of metabolic activity. Due to their higher solubility, salts (such as sodium or potassium lactates) are more commonly used than the organic acids. The studies showed that a combination of different acids or salts at various stages of processing worked best. Therefore, while the study did look at the use of some acids that are already on the National List of Allowed and Prohibited Materials at §205.605, many combinations included acids or salts not on the National List, such as sodium diacetate, acetic acid, benzoic acid, propionic acid, and lauricarginate (Campos, et al. 2011).

<u>Lactic Acid Cultures</u>:
Sebranek (2007) explored the use of lactic acid cultures as natural antimicrobials. Nitrate-reducing bacterial culture has been used in meat curing for over 100 years and has been commercially available for several years. Most applications of these cultures have been for dry sausage, where a long-term reservoir of nitrite during drying is desirable, and where subtle flavor contributions from the culture are considered important.

Sebranek (2007) points out that in the late 1800s it was discovered that nitrite, as opposed to nitrate, was the true curing agent in meat and that nitrates (e.g., sodium or potassium nitrate), which were historically used as the curing agents, were converted to nitrite by nitrate-reducing bacteria. A general shift from nitrate to nitrite as the primary curing agent for cured meats occurred because faster curing times led to increased production capacity. One of the major roles that nitrates/nitrites play in cured meat products is as antibacterial agents, most importantly controlling *Clostridium botulinum*, and also contributing to the control of *Listeria Monocytogens*.

In the study by Sebranek (2007), the lactic acid starter cultures used for fermented sausage, primarily *Lactobacillus plantarum* and *Pediococcus acidilactici* , were not found to reduce nitrate. However, cultures of coagulase negative cocci such as *Kocuria* (formerly *Micrococcus) varians, , Staphylococcus carnosus* and others will reduce nitrate to nitrite. These organisms can achieve nitrate reduction at 15 -20°C but are much more effective at temperatures over 30°C. Research has shown that a celery juice powder/starter culture treatment was an effective alternative to the direct addition of sodium nitrite to small-diameter, frankfurter-style cured sausage, but that incubation time at 38°C is an important factor for product quality. The celery juice powder/starter culture treatment was also effective for hams, but in this case the quantity of celery juice powder was critical. For large diameter products such as hams, it appears that the slow temperature increase that is part of a typical thermal process may provide enough time for the culture to achieve nitrate-to-nitrite reduction. Further, the delicate flavor profile of hams makes these products more susceptible to flavor contributed by vegetable products (Sebranek 2007).

Bacteriophages:

Bacteriophages (microorganisms) are utilized as an antimicrobial to control bacteria during the production of foods on the farm, on perishable foods post-harvest, and during food processing. Phages have been applied to control the growth of pathogens such as *Listeria monocytogenes*, *Salmonella*, and *Campylobacter jejuni* in refrigerated foods such as fruit, dairy products, poultry, and red meats. Bacteriophage products are typically sprayed directly on food products prior to packaging (GRN 468; GRN 218; (OMRI 2014b)).

In the Federal Register of August 18, 2006, the FDA announced that it had approved the use of a bacteriophage preparation made from six individually purified phages to be used on RTE meat and poultry products as an antimicrobial agent against *Listeria monocytogenes*. The rule is in response to a food additive petition submitted in 2002 from Intralytix, Inc.

In the Q&A regarding bacteriophage preparations for RTE meat and poultry products, the FDA clarified the following:

1. Bacteriophages (phages) are viruses that infect only bacteria and do not infect mammalian or plant cells. Phages are ubiquitous in the environment, and humans are routinely exposed to them at high levels through food and water without adverse effect.
2. The additive that was approved is a mixture of equal proportions of six phages specific against *L. monocytogenes*. The petitioner's rationale for incorporating six phages in one formulation is to minimize the possibility of *L. monocytogenes* developing resistance to the additive. The approved phage preparation is reported to be effective against 170 strains of *L. monocytogenes*.
3. The phage preparation will be used in meat and poultry processing plants for spray application to the surface of RTE meat and poultry products, such as lunch meats and hot dogs, to kill *Listeria*. The phage preparation will be applied to the surface of RTE meat and poultry products at a level not to exceed 1 ml per 500 cm^2 food surface just prior to packaging.
4. Based on information submitted to the FDA by the petitioner, the FDA concluded that the additive does not pose any safety concerns, providing that it complies with the identity and specifications in the regulation.

(FDA 2014)

As stated above, phage preparations are sprayed onto the surface of RTE meat and poultry products. According to the product data information for the LISTEX™ product, phages are considered processing aids and do not have to be declared on the finished product label (Micreos B.V. 2012). This is a different situation from sodium lactate and potassium lactate, which are added to meat as ingredients at the rate of 1% to 4.8% as prescribed by USDA-FSIS regulations, depending on the product (Applegate Farms 2004).

Phages can be used to address post-lethality contamination of *Listeria monocytogenes* under 'Alternative 2' or 'Alternative 1' anti-Listeria protocols as defined by the USDA FSIS. Phages have been confirmed as GRAS by the FDA and do not require labeling when used as processing aids. Furthermore, phages are suitable for natural and organic products (OMRI 2014b) and, according to Micreos B.V. (2012), can be integrated easily within the daily routine of the normal production process.

According to Hagans (2012), the LISTEX™ phage, which is active against thousands of strains of *Listeria monocytogenes*, reportedly withstands a wide range of food processing conditions; does not affect organoleptic properties of the treated products such as taste, texture, or color; leaves starter cultures unaffected and is non-corrosive. This phage, selected from Micreos' proprietary collection of food-grade phages, shows bacteriocidal effects that can be measured within hours. A dose-dependent control of *Listeria monocytogenes* is typically observed during shelf life (Hagens 2012).

Research into the efficacy of natural microbials in controlling food pathogens while still maintaining sensory attributes appears to be ongoing. Many factors, including pH, storage time and temperature, type of food product, fat and sugar levels, and exposure to light all play a role in determining the best combinations of additives and processing methodologies. Current research appears to be open to assessing the safety of these alternative products.

<u>Evaluation Information #13:</u> Provide a list of organic agricultural products that could be alternatives for the petitioned substance (7 CFR § 205.600 (b)(1)).

Lactic Acid

Currently, lactic acid is not being produced organically. It is a nonagricultural material and has been historically allowed in organic handling both domestically and internationally for many years.

Sodium Lactate and Potassium Lactate

As stated in #12, research into the use of natural antimicrobials in organic and natural meat products is being done with promising results. Agricultural antimicrobial alternatives are discussed below.

<u>Celery Powder</u>:

The USDA Organic Regulations do not permit the addition of nitrite to organic processed meat. Alternative methods like the use of celery powder, which is listed on at 7 CFR Part 205.606 and allowed for use in products labeled as "Organic" only when an organic form is not commercially available, are commonly used in meat products. Xi, Sullivan, & Sebranek (2013) conducted trials with celery powder containing 12,000 ppm of nitrite. The concentration of nitrite when the celery powder was used at 0.4% of the frankfurter formulation resulted in 48 ppm of nitrite added to the frankfurter mixture. In a conventional curing process, 156 ppm of nitrite is added. The research found that the celery powder achieved the expected color, flavor and other properties of cured meats, but it resulted in lower nitrite levels than occurred with the use of synthetic preservatives.

<u>Cranberry, Cherry, Lime, Vinegar Powders</u>:

In a study by Iowa State University in 2013, powdered concentrates from cranberries, cherries, limes and a blend of cherry, lime and vinegar were evaluated alone and in various combinations for antimicrobial impact on the growth of *L. monocytogenes* in naturally cured frankfurters. Naturally cured frankfurters were manufactured for this study using 0.4% celery powder (Xi, Sullivan and Sebranek 2013).

The results showed that cranberry powder at 3% of the formulation, combined with celery powder, achieved inhibition of *L. monocytogenes* following the inoculation of naturally cured frankfurters that was equivalent to that of conventionally cured frankfurters during 49 days of refrigerated storage. Cranberry powder at 1% and 2% in combination with other natural antimicrobials inhibited growth for up to 35 days, while the naturally cured frankfurters without additional antimicrobial ingredients showed growth after 28 days. However, quality assessment of the products showed that 3% cranberry powder was detrimental to the color and sensory and textural attributes of the frankfurters, possibly due to the acidic nature of the cranberry concentrate. Addition of phosphate to the formulation increased the product pH but also reduced the antimicrobial impact of the cranberry powder. Therefore, Xi, Sullivan, & Sebranek (2013) concluded that, while cranberry concentrate has potential as a natural antimicrobial, it is necessary to develop a means of compensating for the acidic nature of this ingredient in order to achieve practical applications in organic cured meat products (Xi, Sullivan and Sebranek 2013).

More research needs to be done in this regard. In addition, in order for the meat to maintain its organic status, the cranberry powder would also need to be a certified organic ingredient and, per the requirements at section 205.606, attempts would need to be made to source organic celery powder.

Vinegar, Lemon Powder, Cherry Powder:
Similar studies were conducted on ham by Iowa State University in 2010 using combinations of vinegar, lemon powder and cherry powder blend. Eight ham treatments were manufactured, processed, sliced and packaged, and all of the ham treatments contained the base ingredients of ground ham, salt, sugar and water. Samples were prepared with various treatments: salt, sugar and water; sodium erythorbate, sodium nitrite and lactate/diacetate blend; a natural nitrate source and a nitrate reducing starter culture *(Staphlococcus camosus);* a natural nitrate source, a nitrate reducing starter culture *(Staphlococcus camosus)* and an antimicrobial (vinegar, lemon powder and cherry powder blend); a natural nitrate source, a nitrate reducing starter culture *(Staphlococcus camosus)* and another antimicrobial (cultured corn sugar and vinegar blend); a natural source of nitrite without additional antimicrobials; a natural nitrite source and an antimicrobial (vinegar, lemon powder and cherry powder blend); and a natural nitrite source and another antimicrobial (cultured corn sugar and vinegar blend) (Niebuhr, et al. 2010).

According to the research, the addition of the antimicrobials appeared to improve control of *L. monocytogenes,* but these products demonstrated a slight variation of inhibitory activity, suggesting that other inhibitory factors are involved. The treatments with a natural nitrate source and starter culture had the highest residual nitrite, followed by traditionally cured samples. Residual nitrite declined with time. The samples with the vinegar, lemon powder and cherry powder blend had the highest pH, followed by those with a natural nitrite source and no antimicrobials. Traditionally cured samples had the lowest pH. Ham with the direct addition of sodium nitrite (control) had the lightest color of the cured samples, and the treatments with the vinegar, lemon powder and cherry powder blend were the darkest. Traditionally cured samples had the reddest color, followed by those with a natural nitrate sources and starter culture. These were said to be related to the residual nitrite level found in the product. No differences were found in the water activity, salt, protein, fat or moisture (Niebuhr, et al. 2010).

Essential Oils:
Campos, et al. (2011) looked at the effectiveness of essential oils in controlling *L. monocytogenes*. The results of these studies were promising; however, in many instances, combinations of additives or preservative treatments worked best because the efficacy of the antimicrobials can be influenced by the chemical composition and the physical conditions of various foods.

Essential oils (EOs) are oily liquid mixes of volatile and complex compounds that are extracted from different parts of aromatic plants. They are synthesized by plants as secondary metabolites and can be obtained mainly by steam distillation or super critical fluid extraction. Essential oils can contain 20-60 components, depending on the material they come from and the extraction method used. Terpenes and terpenoids make up the majority group, and aromatic and aliphatic compounds of low molecular weight, the minority.

Campos, et al. (2011) examined EOs for their activity against *Listeria* growth in laboratory media, and it was found that EOs of bay, coriander, cinnamon, clove, licorice, nutmeg, pepper, oregano, winter savory, spruce and thyme showed the highest inhibitory activity. The effectiveness of oils of basil, lemon balm, marjoram, mastic tree, rosemary and sage were lower than those mentioned above, whereas *Listeria* showed high resistance to EOs of aniseed, caraway, fennel, garlic, ginger, onion and parsley.

According to the research, the antimicrobial activity of EOs mainly depends on their composition; however, the mechanism of antimicrobial action of EOs is not well known. Inhibitory actions are more related to the main than the minor components. The main components often consist of: carvacrol, thymol, linalool, eugenol, trans-cinnamaldehyde, p-cymene, 1,8-cineole (eucalyptol) and γ-terpinene. However, the minor components can modulate the antimicrobial action of the main components, because the research suggests that several components of EOs are involved in the fixation on cell walls and cellular distribution. It's reported that EO components may degrade the cell wall, damage the cytoplasmic membrane and proteins of the membrane, leak vital intracellular compounds, coagulate cytoplasm and deplete the proton motive force, and that EOs also interact with one another, potentially leading to synergistic antimicrobial effects between various oils. For example, Campos, et al. (2011) observed that the growth of *L. monocytogenes* was suppressed more when a combination of oils was used (oils of oregano and rosemary; oils of basil, rosemary or sage; and oils of rosemary and licorice) than when these oils were used alone.

Further results in various samples suggested that EOs have lower activity in foods with high fat content. This may be due to: (i) EO dissolution in the lipid fraction of the food, decreasing the concentration in the aqueous phase, together with antimicrobial action; (ii) the reduced water content in foods, particularly in fatty foods, in relation to culture media, which may slow down the movement of the preservative to the active site in the microbial cell; and (iii) the presence of fat in the food which may produce a protective layer around the bacteria (Campos, et al. 2011).

Storage temperature, pH, physical structure of food, fat, protein, sugar content, and sensory properties all need to be taken into account when considering whether EOs will be affective for controlling pathogens. It was reported that chicken frankfurters treated with 2%v/w of clove oil were unacceptable to the consumer, whereas samples with 1% were accepted. The latter level had effective antilisterial activity in the food. It was found that combining EOs would allow the use of lower levels to reduce *Listeria* growth, minimizing the unacceptable sensory changes in the food. Indirect uses of EOs, for example in water to wash vegetables similar to the use of chlorine, or in the impregnation of porous surface of wood in cheese ripening to improve sanitary safety, are also being considered.

According to the 2013 list of certified USDA organic operations (USDA 2013), the following agricultural products, which are identified above as natural antimicrobials for meat applications, are produced organically:

Table 4: Possible Antimicrobial Substances Produced Organically (USDA 2013)

Organic Agricultural Product	Number of NOP-certified operations certified for product
Cranberry Extract	1
Cranberry Powder	8
Oregano Extract	2
Celery Powder (currently listed on 205.606)	2
Lemon Powder	8
Cherry Powder (Acerola)	59
Vinegar Powder	0
Basil Oil	13
Rosemary Oil	13
Licorice Oil	0
Sage Oil	26
Clove Oil	3
Nutmeg Oil	14

Sebranek (2007) warned that while agricultural and/or natural antimicrobials may be effective in one way, they may be ineffective in another, and stresses staying open to further research in order to ensure that food safety of these materials is properly assessed. The research suggests that:

1. Acidulants such as vinegar have the potential to accelerate nitrite reactions because of the impact of pH. Reducing pH in these products is also a concern for reduced moisture retention, because phosphates and many of the traditional water binders cannot be used for natural or organic products.
2. Cherry powder is high in ascorbic acid, which functions as a strong nitrite reducer but does not have as great an impact on pH.

3. Natural antioxidants such as rosemary may be used to provide flavor protection and to retard lipid oxidation in processed meats. However, these compounds do not contribute directly to nitrate/ nitrite reactions in meat systems.
4. Liquid sources of naturally occurring nitrates (vegetable juices) also pose some manufacturing issues. Typically, most of these liquids are not shelf-stable, and are supplied in frozen form. Second, the added water that is a component of the juices must be considered (Sebranek 2007).

<u>Multi-barrier Preservation Systems</u>**:**
Apostolidis, Kwon, & Shetty (2008) studied the efficiency of water soluble phenolic extracts of oregano and cranberry in combination with sodium lactate for control of *L .monocytogenes*. In both broth and cooked meat studies, the results indicated that the combination of water soluble extracts of oregano and cranberry, at a ratio of 50:50 and a concentration of 750 ppm, with 2% sodium lactate had the best inhibitory effect in the tested strain (Apostolidis, Kwon and Shetty 2008).

A similar study looked at the efficacy of three natural antimicrobial ingredients, a 1.5 % vinegar-lemon-cherry powder blend, a 2.5 % buffered vinegar, and a 3.0 % cultured sugar-vinegar blend, on 14 ham and turkey samples prepared with various methods of preservation and inoculated with *L. monocytogenes*. While it was found that the addition of either vinegar-lemon-cherry powder blend or buffered vinegar delayed *L. monocytogenes* growth for an additional 2 weeks, the addition of cultured sugar-vinegar blend delayed growth for an additional 4 weeks for both ham and turkey. The greatest *L. monocytogenes* delay was observed in roast beef containing any of the three antimicrobial ingredients, with no growth detected through 12 weeks at 4°C for any of the treatments. *L. monocytogenes* grew substantially faster in products stored at 7°C than at 4°C. These data suggest that antimicrobial ingredients from a natural source can enhance the safety of RTE meat and poultry products, but their efficacy is improved in products containing nitrite and with lower moisture and pH (McDonnell, Glass and Sindelar 2013).

While current research suggests that natural plant extracts can be effective in controlling pathogens in meat products, the most favorable results tend to result from multiple-barrier food preservation systems, which use combinations of agricultural and/or natural antimicrobials and sodium or potassium lactate (or other synthetic antimicrobial ingredients). However, decreasing the shelf life of a product in order to accommodate the strict use of natural antimicrobials is another option.

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