

Lactic Acid, Sodium Lactate, and Potassium Lactate

Handling/Processing

Identification of Petitioned Substance

22	(AMD) Lactic Acid 50% FCC, ADM Lactic Acid
23	88% USP Heat Stable (fermented), ADM Lactic
24	Acid, 88% FCC
25	
	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

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)

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,

52 NOP requests that the NOSB take up the petitions for sodium lactate and potassium lactate for consideration
53 for inclusion on the National List. (McEvoy 2014)
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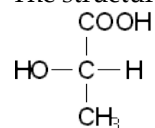
55 The original 2004 petition was submitted for the following use: "Both Sodium Lactate and Potassium Lactate
56 are used in meat processing as a pathogen inhibitor. Product comes as a liquid and is added to meat as an
57 ingredient at the rate of 1% to 4.8% as prescribed by USDA-FSIS regulations, depending on the product.
58 Whether one uses sodium lactate or potassium lactate is at the discretion of the processor or by the
59 requirements of the recipe - i.e. Low sodium products" (Applegate Farms 2004).
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61 Characterization of Petitioned Substance

62 Composition of the Substance:

63 Lactic Acid

64 The structural formula of lactic acid is:

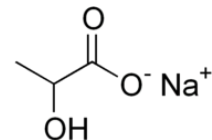


66 Figure 1: The structural formula of lactic acid
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69 Lactic acid is 2-hydroxypropionic acid. Lactic acid occurs naturally in two optical isomers, D(-) and L(+)-
70 lactic acids. Since elevated levels of the D-isomer are harmful to humans, L(+)-lactic acid is the preferred
71 isomer in food and pharmaceutical industries (Vijayakumar, Aravindan and Viruthagiri 2008). Lactic acid is
72 a colorless, syrupy liquid or white to light yellow solid or powder (Joint FOA/WHO Expert Committee on
73 Food Additives (JECFA) 2004). The Food Chemicals Codex specifies that food grade lactic acid should
74 contain not less than 95% or more than 105% of the labeling concentration (Life Sciences Research Office
75 1978). Lactic acid is commercially available at different grades (qualities). They include technical grade lactic
76 acid (20 -80%), food grade lactic acid (80%), pharmacopoeia grade lactic acid (90%), and plastic grade lactic
77 acid. Pharmaceutical and food grade lactic acids are considered to be most important in the lactic acid
78 production industry.
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80 Sodium Lactate

81 The structural formula for sodium lactate is:

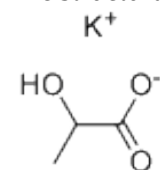


82 Figure 2: The structural formula of sodium lactate
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85 Sodium lactate is hygroscopic. It is derived from natural L(+) lactic acid, a weak acid having a dissociation
86 constant of $1.389 \cdot 10^{-4}$ at 22°C ($\text{pK}_a=3.857$). Sodium lactate has a content of 59-61% (w/w) and a
87 stereochemical purity (L-isomer) of at least 95% (Houtsma 1996).
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89 Potassium Lactate

90 The structural formula is:



91 Figure 3: The structural formula of potassium lactate
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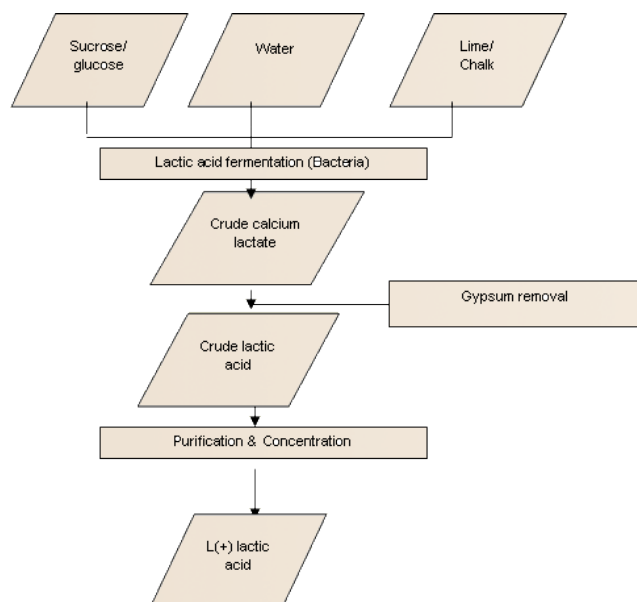
94 Potassium lactate is an anhydrous, clear, hygroscopic and syrupy solution, which complies with Food
95 Chemical Codex V. It has a lactate content of 59-61% (w/w), a stereochemical purity (L-isomer) of at least

96 95%, a pH of 6.5 – 8.5, and a concentration of 60% solids by weight in purified water. The crystalline
 97 potassium salt of lactic acid is hygroscopic and extremely difficult to isolate (Joint FAO/WHO Expert
 98 Committee on Food Additives (JECFA) 2003).

100 **Source or Origin of the Substance:**

101 **Lactic Acid**

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



111
 112 Figure 4 – Lactic Acid Production (Corbion Purac 2014)

114 **Sodium Lactate and Potassium Lactate**

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

118 **Properties of the Substance:**

119 **Lactic Acid**

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

122
 123 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 ₂ O)	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

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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 n ₂₀ /D
Solubility in water (g/100 g H ₂ O)	miscible

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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 ₂ O)	viscous

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Specific Uses of the Substance:

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Lactic Acid

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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).

145 Common uses include, but are not limited to:

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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 Mesenteric 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.

- 157 10. Use of buffered¹ lactic acid improves the taste and flavor of many beverages, such as soft drinks,
158 mineral water and carbonated fruit juices.
- 159 11. In breweries, lactic acid is used for pre-adjustments during the mashing process and during wort
160 cooking.
- 161 12. Acidification of lager beer with lactic acid improves the microbial stability as well as flavor.
- 162 13. It is used in processing of meal in sauces for canned fish, to improve the taste and flavors and to
163 mask amine flavor from fish meal.
164 (Vaishnavi Bio-Tech Limited 2011)

165
166 Lactic acid is also marketed for a myriad of other non-food applications. These include, but are not limited
167 to, use as an industrial chemical, as an acidulant, in pharmaceutical, leather, and textile industries, and as a
168 chemical feedstock. Another application of lactic acid is its use for biodegradable and biocompatible lactate
169 polymers, such as polylactic acid (Vijayakumar, Aravindan and Viruthagiri 2008).
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171 Sodium Lactate and Potassium Lactate

172 Sodium and potassium lactate were petitioned for use as pathogen inhibitors for processed meat. The 2004
173 petition explains that "whether one uses sodium lactate or potassium lactate is at the discretion of the
174 processor or by the requirements of the recipe - i.e. Low sodium product." (Applegate Farms 2004). The
175 main argument in the petition is that sodium and potassium lactates are some of the few known
176 antimicrobials for meat products that are recognized by the USDA Food Safety and Inspection Service
177 (USDA-FSIS) to inhibit growth of *Listeria monocytogenes*, along with *E.coli*, *Salmonella* and other pathogens.
178 Sodium and potassium lactates can replace nitrates/nitrites in meat products and are generally recognized
179 as safe (GRAS).
180

181 The petition states that the USDA-FSIS declared in 9 CFR Part 430, "Control of *Listeria monocytogenes* in
182 Ready-to-Eat (RTE) Meat and Poultry Products; Final Rule" that "On the question of a 'Zero Tolerance' for *L.*
183 *monocytogenes* and particularly with respect to RTE products that support growth of the pathogen, FSIS
184 currently regards any amount of the organism as a product adulterant." Therefore, sodium and potassium
185 lactate can be used during the production of RTE meat and poultry products to remain in compliance with
186 the USDA-FSIS requirements.
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188 In addition, sodium lactate and potassium lactate are permitted in the U.S. as flavoring agents in meat,
189 poultry and food products, and as emulsifiers, flavor enhancers, adjuvants, humectants and pH control
190 agents. (Purac 2011)
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192 An increase in sodium lactate levels from 0-4% in cooked beef roasts was found to result in a darker red
193 color with less gray surface, and improved juiciness and tenderness of the meat product (Houtsma 1996).
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195 Approved Legal Uses of the Substance:

196 Lactic Acid

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

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

262 of tyrosinase and thereby reducing the production of melatonin (Vijayakumar, Aravindan and Viruthagiri
263 2008).

264

265 **Sodium Lactate**

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

273

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

278

279 The addition of sodium lactate has been shown to increase the meat pH to produce a darker colored lean, the
280 cut of the meat containing the least fat. The darker color meat containing sodium lactate also has been shown
281 to stabilize with storage. This stabilization of meat color with storage is most likely due to the higher pH that
282 provides some protection against oxidation during meat storage. Myoglobin is the pigment that gives meat
283 its red color. When myoglobin is oxidized, it turns brown in the "metmyoglobin" state. Contributing factors
284 for oxidation of myoglobin are pH, the amount of exposed light, microbial growth and time. At a higher pH,
285 oxidation of myoglobin is not as rapid. As sodium lactate addition has been associated with increasing meat
286 pH to increase water-holding capacity and reduce cook losses, the resulting meat is more tender (Miller
287 2010).

288

289 There are three proposed mechanisms by which sodium lactate can have an antimicrobial affect. The first is
290 changing water activity (aw). The addition of sodium lactate lowers the water activity of the meat and
291 thereby slows microbial growth. The second mechanism occurs as sodium lactate passes through the cell
292 membrane and lowers intracellular pH, and the third takes place as sodium lactate affects cellular
293 metabolism by inhibiting ATP² generation. The lactic acid portion of sodium lactate has antimicrobial
294 properties, as it can be incorporated into the microbial cell. Lactic acid then interferes or slows down the
295 normal metabolic process that generates energy in the cell. This metabolic process is called glycolysis. The
296 sodium ion also has some antimicrobial effects (Miller 2010).

297

298 **Potassium Lactate**

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

306

307 **Combinations of the Substance:**

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

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

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

313 ingredients can be combined with lactic acid to form buffered lactic acid, which contains calcium lactate and
314 silicon dioxide. Calcium lactate is the calcium salt of lactic acid and is produced during lactic acid
315 production. Silicon dioxide appears on the National List of Allowed and Prohibited Substances at 7 CFR Part
316 205.605(b) as “Permitted as a defoamer. Allowed for other uses when organic rice hulls are not commercially
317 available” (USDA 2014).

318
319 Sodium lactate or potassium lactate may be combined with sodium diacetate. The reason for this is that low
320 levels of sodium diacetate (i.e., below 0.2%) lower the pH of the surface of meat products and therefore
321 decrease microbial growth. Research suggests that sodium diacetate in combination with other ingredients,
322 such as sodium lactate or potassium lactate, is even more effective in retarding microbial growth and
323 reducing the growth of some major foodborne pathogens, including *Listeria monocytogens*, than the addition
324 of sodium diacetate to meat products alone. The antilisterial activity of sodium diacetate is not only due to
325 the pH lowering effect, but to the activity of the acetate ion on listerial growth. Sodium diacetate is a GRAS
326 substance and contains 60% sodium acetate and 40% acetic acid (Miller 2010).

327
328 There is no evidence to indicate that buffered lactic acid and sodium/potassium lactate-sodium diacetate
329 combinations are harmful to humans or the environment.
330

Status

332 **Historic Use:**

333 **Lactic Acid**

334 Lactic acid was reviewed and recommended for listing on the National List by the NOSB in 1995 (Theuer
335 1995). It is currently listed at §205.605(a) of the National List of Allowed and Prohibited Substances under
336 “Acids (Alginic; Citric – produced by microbial fermentation of carbohydrate substances; and Lactic).”
337 Historical use in organic food processing is as a multipurpose food ingredient, as an antimicrobial agent, a
338 curing and pickling agent, a flavoring agent, a pH control agent, and for other uses already described in this
339 report.
340

341 **Sodium Lactate and Potassium Lactate**

342 Sodium lactate and potassium lactate were petitioned for inclusion on the National List of Allowed and
343 Prohibited Substances, 7 CFR 205.605, on January 5, 2004. On January 22, 2004, the NOP notified the
344 petitioner that the petitions were not necessary since the materials were combinations of materials already
345 on the National List (i.e., lactic acid combined with sodium hydroxide and lactic acid combined with
346 potassium hydroxide). Therefore, since the NOP’s letter to the petitioner was released, both sodium lactate
347 and potassium lactate have been allowed for use in organic processing. It is not clear whether certifiers have
348 allowed it for all applications or just for meat production.
349

350
351 On June 25, 2014, the NOP issued a memorandum to the National Organic Standards Board (NOSB)
352 regarding the regulatory statuses of sodium lactate and potassium lactate. In that memorandum, the NOP
353 acknowledged that the interpretation published on January 22, 2004, was not consistent with previous NOSB
354 recommendations on classification of materials, and they requested that the NOSB take up the petitions for
355 these two substances for consideration for inclusion on the National List (McEvoy 2014).
356

357 **Organic Foods Production Act, USDA Final Rule:**

358 **Lactic Acid**

359 Lactic acid does not appear specifically in OFPA. It is permitted as a nonagricultural (nonorganic) substance
360 allowed as an ingredient in or on processed products labels as “organic” or “made with organic (specified
361 ingredients of food group(s))” per 7 CFR Part 205.605(a) as “Acids (Alginic; Citric – produced by microbial
362 fermentation of carbohydrate substances; and Lactic)” (USDA 2014).
363

364 **Sodium Lactate and Potassium Lactate**

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

368 However, the individual materials combined to produce both sodium lactate (e.g., lactic acid and sodium
369 hydroxide) and potassium lactate (e.g., lactic acid and potassium hydroxide) are included at 7 CFR Part
370 205.605. Sodium hydroxide and potassium hydroxide are allowed synthetic materials. Sodium hydroxide
371 was reviewed and recommended for listing on the National List by the NOSB in 1995. Potassium hydroxide
372 was recommended for listing on the National List by the NOSB in 2001.

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374 **International**

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

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

379

380 **Canada - Canadian General Standards Board Permitted Substances List**

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

384

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

391

392 **CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing 393 of Organically Produced Foods (GL 32-1999)**

394 Lactic acid is permitted by the CODEX Alimentarius per Table 3, Ingredients of Non-Agricultural Origin
395 Referred to in Section 3 of These Guidelines, as follows: Lactic Acid (L- D- and DL-) is allowed in "**Food of
396 Plant Origin:** 04.2.2.7 Fermented vegetables (including mushrooms and fungi, roots and tubers, pulses and
397 legumes and aloe vera), and seaweed products, excluding fermented soybean products, of food category
398 12.10." Lactic acid is also allowed in "**Food of Animal Origin:** 01.0 Dairy products and analogues, excluding
399 products of food category 02.0. 08.4, and Edible casings (e.g. sausage casings)."

400

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

409

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

413

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

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

419

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

422

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

425

426 **Japan Agricultural Standard (JAS) for Organic Production**

427 Lactic acid is included in JAS Notification No. 1606 of the Ministry of Agriculture, Forest and Fisheries, of
428 October 27, 2005, revised 2012:Table 1 – Additives as follows: “Limited to be used for processed vegetable or
429 rice products, for sausage as casing, for dairy products as coagulating agent, and for cheese in salting as pH
430 adjuster.”

431

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

433

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

436

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

439

440 **International Federation of Organic Agriculture Movements (IFOAM)**

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

444

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

447

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

451

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

453

454 **Evaluation Questions for Substances to be used in Organic Handling**

455

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

460

461 **Lactic Acid**

462 To produce nonsynthetic lactic acid commercially, the most common manufacturing process is via
463 carbohydrate fermentation using homolactic organisms such as *Lactobacillus delbrueckii*, *L. bulgaricus*, and *L.*
464 *leichmanii*. A wide variety of carbohydrate sources, e.g., molasses, corn syrup, whey, dextrose, and cane or
465 beet sugar, can be used. Proteinaceous and other complex nutrients required by the organisms are provided
466 by corn steep liquor, yeast extract, soy hydrolysate, etc. If starch is used, the starch needs to be enzymatically
467 hydrolyzed prior to fermentation. Production of lactic acid from starch materials requires a pretreatment
468 process for gelatinization and liquefaction, which is carried out at a temperature between 90 and 130°C for
469 15 min, followed by enzymatic saccharification to glucose (enzymatic hydrolysis), followed by conversion of
470 glucose to lactic acid by fermentation (Zhang, Jin and Kelly 2007).

471

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

476

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

482
483 Vijayakumar, Aravindan, and Viruthagiri (2008) identify the various different ways in which lactic acid can
484 be recovered and purified:

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

504
505 The Organic Materials Review Institute (OMRI) has also identified an alternative process where ethanol is
506 added to the refined material, which reacts with the lactic acid to make ethyl lactate. The ester is purified
507 (separated) by distillation and then hydrolyzed into ethanol and lactic acid. Ethanol is evaporated out to
508 complete concentration of lactic acid (OMRI 2014a).

509
510 Alternate lactic acid production, which is not yet commonly employed because it is still being researched,
511 can occur using various fungal species of the *Rhizopus* genus. Zhang, Jin, & Kelly (2007) review recent
512 research in process engineering, metabolic and enzymatic mechanisms, and molecular technologies
513 associated with lactic acid production by the *Rhizopus* fungi.

514
515 In this system, the glucose is the preferred carbon source for L-lactic acid production by *Rhizopus* species,
516 followed by starch material. In contrast to the processing described above, simultaneous saccharification and
517 fermentation (SSF) integrates the saccharification and fermentation steps (Zhang, Jin and Kelly 2007).

518 519 **Sodium Lactate**

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

522 523 **Alternative Production of Sodium Lactate**

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

528
529 Another alternative procedure for preparing sodium lactate without the use of sodium hydroxide consists
530 briefly of the following steps: First the traditional fermentation process to produce lactic acid is employed,
531 but the killing step is carried out at a temp of 180°F with sufficient lime added. The resulting calcium lactate

532 liquor is then separated by filtration from the insoluble matter present. The calcium lactate liquor at this
533 stage usually has a dark, reddish brown color, which can be partly reduced by bleaching with a vegetable
534 carbon. Either the bleached or unbleached liquor is then converted to sodium lactate by reacting the liquor
535 with sodium carbonate, forming the insoluble salt, calcium carbonate. The insoluble calcium carbonate is
536 separated from the alkaline sodium lactate liquor by filtering and the pH of the filtered sodium lactate is
537 then adjusted to the proper value by adding a suitable acid. The sodium lactate without further chemical
538 treatment is concentrated to the desired concentration, usually 50% sodium lactate. Prior to the
539 concentration step or after a partial concentration, bleaching of the sodium lactate solution with vegetable
carbon is often used (Morgan and Goodman 1939).

541 Potassium Lactate

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

544

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

549

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

553

554 Lactic Acid

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

561

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

568

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

573

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

579

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

584

585 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.

Evaluation Question #3: 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 *Lactobacillus* 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.

Evaluation Question #4: 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

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

642 (Food and Drug Administration 2008)

643

644 **Potassium Lactate**

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

647 1. The ingredient is used as an emulsifier as defined in 21 CFR 170.3(o)(8);

648 2. as flavor enhancer as defined in 21 CFR 170.3(o)(11);

649 3. as flavoring agent or adjuvant as defined in 21 CFR 170.3(o)(12);

650 4. as humectant as defined in 21 CFR 170.3(o)(16); and

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

652 (Food and Drug Administration 2008)

653

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

657

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

662

663 **Lactic Acid**

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

668

669 **Sodium Lactate and Potassium Lactate**

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

673

674 The USDA Food Standards and Labeling Policy Book:

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

686

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

692

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

695 regardless of whether it can be shown that any form of lactate is from a natural source and is not
696 more than minimally processed, the use of lactate (sodium, potassium, and calcium) may conflict
697 with the meaning of “natural” because it may be having a preservative effect at levels of use
698 associated with flavoring. Thus, listing “sodium lactate (from a corn source)” in the previous entry
699 may have been in error, at least without qualifying the listing by stating that the use of this
700 ingredient or any ingredient known to have multiple technical effects needs to be judged on a case-
701 by-case basis at the time of label approval to assess that the intended use, level of use, and technical
702 function are consistent with the 1982 policy.... Therefore, FSIS has removed the reference to sodium
703 lactate from this guidance but will judge claims that foods to which a lactate has been added can be
704 characterized as “natural” on a case-by-case basis, pending the outcome of a rulemaking on the use
705 of “natural” that the Agency intends to initiate in the near future.” (USDA FSIS 2005)
706

707 **Evaluation Question #6: Describe whether the petitioned substance will be used primarily to recreate or**
708 **improve flavors, colors, textures, or nutritive values lost in processing (except when required by law) and**
709 **how the substance recreates or improves any of these food/feed characteristics (7 CFR § 205.600 (b)(4)).**
710

711 Lactic Acid

712 While lactic acid is not used to recreate or replace flavors, colors, textures, or nutritive values lost during
713 processing, its major functions are as a flavor or flavor enhancer, and to assist with texture and stability in
714 certain food products. As stated previously, lactic acid is used to produce a mild and pleasant taste in acid
715 pickles, relishes and salad dressings; improve the taste and flavor of many beverages, such as soft drinks,
716 mineral water, carbonated fruit juices; improve the microbial stability as well as flavor in large-scale beer
717 manufacturing; and improve the taste and flavors in the processing of meal in sauces for canned fish, by
718 masking the amine flavors from fish meal (Vaishnavi Bio-Tech Limited 2011).
719

720 Sodium Lactate and Potassium Lactate

721 Similar to lactic acid, sodium and potassium lactates do not recreate or replace flavors, colors, textures, or
722 nutritive values lost in processing, but are often used to improve or enhance flavors and textures of food
723 products, especially meat. Sodium lactate is known to enhance meat flavor due to the salty taste that it
724 provides, while assisting with color retention and water holding capacity (McClure 2009). Houtsma (1996)
725 reported that an increase in sodium lactate levels from 0% to 4% in cooked beef roasts was found to result in
726 a darker red color with less gray surface, and improved juiciness and tenderness of the meat product.
727 Potassium lactate offers similar attributes but is less salty, appealing to low-sodium applications. McClure
728 (2009) explains that when added to fresh meat, these lactates will delay the development of sour and off-
729 flavors. And for precooked products such as roasts, adding sodium lactate enhances flavor notes, resulting in
730 a stronger beefy flavor. Addition of sodium lactate results in enhancement of overall flavor and beef flavor
731 intensity. By adding sodium lactate to a meat product, the amount of salt (NaCl) could be decreased while
732 still maintaining the desired level of salt flavor.
733

734 **Evaluation Question #7: Describe any effect or potential effect on the nutritional quality of the food or**
735 **feed when the petitioned substance is used (7 CFR § 205.600 (b)(3)).**
736

737 Lactic Acid

738 There is research to support the theory that the addition of lactic acid to unfermented maize products, such
739 as tortillas, significantly improves iron bioavailability without affecting the organoleptic characteristics of
740 these products (Proulx 2007).
741

742 The nutritional benefits of lactic acid fermented foods are well documented. Research suggests that lactic
743 acid fermentation enhances the micronutrient profile of several foods such as yogurt, kefir, fermented
744 vegetables, fruit, legumes and grains. This is said to be caused by the increased bioavailability of amino
745 acids in these foods, particularly lysine and methionine. Vegetables that have undergone lactic acid
746 fermentation, such as sauerkraut and kimchi, often see an increase in Vitamin C and Vitamin A activity. In
747 fermented grains, lactic acid fermentation reduces the naturally occurring phytic acid content, which makes
748 the grains easier to digest and the minerals easier to absorb (Nourished Kitchen 2009).
749

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

804 rely on fewer chemicals, reduce the environmental load, and lessen the carbon footprint of the lactic acid
805 manufacturing process (Corbion 2014).

806
807 **Evaluation Question #10: Describe and summarize any reported effects upon human health from use of**
808 **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)**
809 **(4)).**

810
811 The EPA Screening-Level Hazard Characterization of High Production Volume Chemicals report for Lactic
812 Acid and its salts (2008) concluded that the manufacture and use of natural lactic acid poses a low potential
813 risk to human health (Environmental Protection Agency 2008).

814
815 Lactates have been reported to have low oral toxicity, with a lack of adverse effects in feeding studies in
816 which up to 3,900 mg/kg body weight/day was administered to rats for 2 years. Likewise, lactates were
817 proven to be non-genotoxic and non-mutagenic (Purac 2008).

818
819 In reviewing the safety of lactic acid and its sodium, potassium, and calcium salts, the Joint FAO/WHO
820 Expert Committee on Food Additives (JECFA, 1974) concluded that it was "unnecessary to set ADI limits"
821 for these additives since lactic acid is a normal constituent of food and a normal intermediary metabolite in
822 humans. In another review of the safety of lactic acid and calcium lactate conducted by the Federation of
823 American Societies for Experimental Biology (FASEB, 1978) for the FDA, similar conclusions were drawn by
824 the Select Committee indicating that lactic acid and calcium lactate were safe for use by "individuals beyond
825 infancy when they are used at levels that are now current or that might reasonably be expected in the future"
826 (Purac 2008).

827
828 As described in other sections of this report, the use of lactic acid and its sodium and potassium salts in
829 certain food applications may reduce the risk of foodborne pathogens because of their antimicrobial
830 properties.

831
832 **Evaluation Question #11: Describe any alternative practices that would make the use of the petitioned**
833 **substance unnecessary (7 U.S.C. § 6518 (m)(6)).**

834
835 **Lactic Acid**

836 As discussed previously, lactic acid is produced naturally in many foods by lactic acid bacteria. Lactic acid
837 bacteria are approved for use in organic processing under the listing for microorganisms at 7 CFR Part
838 205.605(a).

839
840 Commercially manufactured lactic acid is a nonsynthetic chemical widely used in the food industry. It is
841 used in a variety of ways that may not easily be substituted by alternative practices, including acidification,
842 as a flavor, and as an antimicrobial agent. For example, although lactic acid can be produced *in situ* by lactic
843 acid bacteria, commercially manufactured lactic acid is often used in place of fermentation (e.g., in cottage
844 cheese production) in order to avoid risks of failure and contamination (Vijayakumar, Aravindan and
845 Viruthagiri 2008).

846
847 **Sodium Lactate and Potassium Lactate**

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

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

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

871 (USDA FSIS 2012)

872
873 While the first alternative is the most conservative approach, the Listeria Rule only applies to products that
874 are RTE and exposed to the environment after the lethality step (which is defined as cooking or another
875 process such as fermentation or drying that results in a product that is safe for consumption without further
876 preparation) (USDA FSIS 2012).

877
878 “Antimicrobial process” is defined in the Listeria Rule as freezing in order to suppress or limit the growth of
879 a microorganism, such as Lm, throughout the shelf life of the product. Other examples include processes
880 that result in a pH or water activity that suppresses or limits microbial growth.

881
882 Processing alternatives include cook-in-bag products, frozen products with safe handling instructions for
883 cooking, strict facility sanitation and testing requirements (under the FSIS’s Listeria Rule (USDA FSIS 2012)),
884 or post processing applications such as high pressure pasteurization and steam/ water pasteurization.
885 While it appears that alternative practices do exist that would make the use of sodium and potassium
886 lactates nonessential, each establishment has products and processes that require specific approaches to
887 control of microorganism contamination. Establishments may even need to utilize multiple alternatives
888 depending on the types of products, facilities, and resources available (USDA FSIS 2012).

889
890 **Evaluation Question #12: Describe all natural (non-synthetic) substances or products which may be used**
891 **in place of a petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (ii)). Provide a list of allowed substances that**
892 **may be used in place of the petitioned substance (7 U.S.C. § 6518 (m) (6)).**

893 **Lactic Acid**

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

898 **Sodium Lactate and Potassium Lactate**

899 Sodium and Potassium Lactates are mainly used as preservatives in meat products due to food safety
900 concerns. Processed nonorganic meat products such as hams, bacon, frankfurters, bologna, and others are
901 commonly cured by addition of sodium nitrite and sometimes sodium nitrate, both of which are prohibited
902 in organic products. Sodium nitrate is a mined mineral sourced primarily from Chile and Peru (ICF
903 International 2011) but can also be produced synthetically by neutralizing nitric acid with sodium carbonate
904 or sodium hydroxide (PubChem Open Chemistry Database 2014). Sodium nitrite is produced from sodium
905 nitrate through the use of heat, light, ionizing radiation and a metal catalyst (PubChem Open Chemistry
906 Database 2014). Both nitrates and nitrites are permitted in the U.S. to be used in curing nonorganic meat and
907 poultry with the exception of bacon, where nitrate use is prohibited. Sodium nitrite is commonly used in the
908 U.S. and around the world (Meats and Sausages 2014). In these processed meat products, sodium and
909 potassium lactate can serve as alternatives to the nitrates and nitrites, which have been associated with
910 nitrosamine formation in cured meats. Nitrates and nitrites are also prohibited for use in meats labeled as
911
912

913 “natural” (Sebranek 2007). There is concern that organic meat products could potentially pose a food safety
914 hazard if they do not contain antimicrobials that are comparable to formulated sodium nitrite (NaNO₂) in
915 concentrations known to be highly effective in inhibiting the growth of many food borne pathogens such as
916 *Listeria monocytogenes* (Niebuhr, et al. 2010). However, more research (as discussed below) into natural
917 antimicrobials in organic and natural meat products is being done with promising results.

918
919 According Niebuhr, et al. (2010), natural antimicrobials often need to be combined or used at higher levels in
920 order to control pathogens, which can have negative impacts on sensory characteristics (color, flavor,
921 aroma). Alternative nonsynthetic additives include vegetable and fruit juice powders that contain natural
922 nitrite, or that modify pH. Other nonsynthetic alternatives include organic acids such as citric and lactic acid,
923 lactic acid starter cultures such as *Staphylococcus carnosus*, vinegar, essential oils and bacteriophages.

924
925 Vinegar, essential oils, and vegetable and fruit juice powders are natural, but they are also agricultural.
926 Therefore, antimicrobials containing these ingredients will be discussed in Question #13 below.

927
928 Research into natural antimicrobials for the control of pathogens such as *Listeria monocytogenes* in foods is
929 ongoing. The ability of *L. monocytogenes* to survive a wide range of adverse conditions, including acidic
930 pH, low temperatures, and high sodium chloride concentrations make the organism difficult to control in
931 food. Several studies that utilize various preservation techniques for the control of *Listeria* in foods are
932 being conducted. Most of them aim at achieving food safety without compromising the sensory and
933 nutritional qualities of foods (Campos, et al. 2011).

934

935 Organic Acids:

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

940

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

952

953 Lactic Acid Cultures:

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

958

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

966

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

979 Bacteriophages:

981 Bacteriophages (microorganisms) are utilized as an antimicrobial to control bacteria during the production
982 of foods on the farm, on perishable foods post-harvest, and during food processing. Phages have been
983 applied to control the growth of pathogens such as *Listeria monocytogenes*, *Salmonella*, and *Campylobacter jejuni*
984 in refrigerated foods such as fruit, dairy products, poultry, and red meats. Bacteriophage products are
985 typically sprayed directly on food products prior to packaging (GRN 468; GRN 218; (OMRI 2014b)).
986

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

991
992 In the Q&A regarding bacteriophage preparations for RTE meat and poultry products, the FDA clarified the
993 following:

- 994 1. Bacteriophages (phages) are viruses that infect only bacteria and do not infect mammalian or
995 plant cells. Phages are ubiquitous in the environment, and humans are routinely exposed to
996 them at high levels through food and water without adverse effect.
- 997 2. The additive that was approved is a mixture of equal proportions of six phages specific
998 against *L. monocytogenes*. The petitioner's rationale for incorporating six phages in one
999 formulation is to minimize the possibility of *L. monocytogenes* developing resistance to the
1000 additive. The approved phage preparation is reported to be effective against 170 strains of *L.*
1001 *monocytogenes*.
- 1002 3. The phage preparation will be used in meat and poultry processing plants for spray application
1003 to the surface of RTE meat and poultry products, such as lunch meats and hot dogs, to
1004 kill *Listeria*. The phage preparation will be applied to the surface of RTE meat and poultry
1005 products at a level not to exceed 1 ml per 500 cm² food surface just prior to packaging.
- 1006 4. Based on information submitted to the FDA by the petitioner, the FDA concluded that the
1007 additive does not pose any safety concerns, providing that it complies with the identity and
1008 specifications in the regulation.

1009 (FDA 2014)

1010
1011 As stated above, phage preparations are sprayed onto the surface of RTE meat and poultry products.
1012 According to the product data information for the LISTEX™ product, phages are considered processing aids
1013 and do not have to be declared on the finished product label (Microcos B.V. 2012). This is a different situation
1014 from sodium lactate and potassium lactate, which are added to meat as ingredients at the rate of 1% to 4.8%
1015 as prescribed by USDA-FSIS regulations, depending on the product (Applegate Farms 2004).

1016
1017 Phages can be used to address post-lethality contamination of *Listeria monocytogenes* under 'Alternative 2' or
1018 'Alternative 1' anti-*Listeria* protocols as defined by the USDA FSIS. Phages have been confirmed as GRAS by
1019 the FDA and do not require labeling when used as processing aids. Furthermore, phages are suitable for

1020 natural and organic products (OMRI 2014b) and, according to Microcos B.V. (2012), can be integrated easily
1021 within the daily routine of the normal production process.

1022 According to Hagans (2012), the LISTEX™ phage, which is active against thousands of strains of *Listeria*
1023 *monocytogenes*, reportedly withstands a wide range of food processing conditions; does not affect
1024 organoleptic properties of the treated products such as taste, texture, or color; leaves starter cultures
1025 unaffected and is non-corrosive. This phage, selected from Microcos' proprietary collection of food-grade
1026 phages, shows bacteriocidal effects that can be measured within hours. A dose-dependent control of *Listeria*
1027 *monocytogenes* is typically observed during shelf life (Hagens 2012).

1028 Research into the efficacy of natural microbials in controlling food pathogens while still maintaining sensory
1029 attributes appears to be ongoing. Many factors, including pH, storage time and temperature, type of food
1030 product, fat and sugar levels, and exposure to light all play a role in determining the best combinations of
1031 additives and processing methodologies. Current research appears to be open to assessing the safety of these
1032 alternative products.

1033

1034 **Evaluation Information #13: Provide a list of organic agricultural products that could be alternatives for**
1035 **the petitioned substance (7 CFR § 205.600 (b)(1)).**

1036

1037 **Lactic Acid**

1038 Currently, lactic acid is not being produced organically. It is a nonagricultural material and has been
1039 historically allowed in organic handling both domestically and internationally for many years.

1040

1041 **Sodium Lactate and Potassium Lactate**

1042 As stated in #12, research into the use of natural antimicrobials in organic and natural meat products is
1043 being done with promising results. Agricultural antimicrobial alternatives are discussed below.

1044

1045 Celery Powder:

1046 The USDA Organic Regulations do not permit the addition of nitrite to organic processed meat. Alternative
1047 methods like the use of celery powder, which is listed on at 7 CFR Part 205.606 and allowed for use in
1048 products labeled as "Organic" only when an organic form is not commercially available, are commonly used
1049 in meat products. Xi, Sullivan, & Sebranek (2013) conducted trials with celery powder containing 12,000
1050 ppm of nitrite. The concentration of nitrite when the celery powder was used at 0.4% of the frankfurter
1051 formulation resulted in 48 ppm of nitrite added to the frankfurter mixture. In a conventional curing process,
1052 156 ppm of nitrite is added. The research found that the celery powder achieved the expected color, flavor
1053 and other properties of cured meats, but it resulted in lower nitrite levels than occurred with the use of
1054 synthetic preservatives.

1055

1056 Cranberry, Cherry, Lime, Vinegar Powders:

1057 In a study by Iowa State University in 2013, powdered concentrates from cranberries, cherries, limes and a
1058 blend of cherry, lime and vinegar were evaluated alone and in various combinations for antimicrobial
1059 impact on the growth of *L. monocytogenes* in naturally cured frankfurters. Naturally cured frankfurters were
1060 manufactured for this study using 0.4% celery powder (Xi, Sullivan and Sebranek 2013).

1061

1062 The results showed that cranberry powder at 3% of the formulation, combined with celery powder, achieved
1063 inhibition of *L. monocytogenes* following the inoculation of naturally cured frankfurters that was equivalent to
1064 that of conventionally cured frankfurters during 49 days of refrigerated storage. Cranberry powder at 1%
1065 and 2% in combination with other natural antimicrobials inhibited growth for up to 35 days, while the
1066 naturally cured frankfurters without additional antimicrobial ingredients showed growth after 28 days.
1067 However, quality assessment of the products showed that 3% cranberry powder was detrimental to the color
1068 and sensory and textural attributes of the frankfurters, possibly due to the acidic nature of the cranberry
1069 concentrate. Addition of phosphate to the formulation increased the product pH but also reduced the
1070 antimicrobial impact of the cranberry powder. Therefore, Xi, Sullivan, & Sebranek (2013) concluded that,
1071 while cranberry concentrate has potential as a natural antimicrobial, it is necessary to develop a means of
1072 compensating for the acidic nature of this ingredient in order to achieve practical applications in organic
1073 cured meat products (Xi, Sullivan and Sebranek 2013).

1074
1075 More research needs to be done in this regard. In addition, in order for the meat to maintain its organic
1076 status, the cranberry powder would also need to be a certified organic ingredient and, per the requirements
1077 at section 205.606, attempts would need to be made to source organic celery powder.
1078

1079 Vinegar, Lemon Powder, Cherry Powder:

1080 Similar studies were conducted on ham by Iowa State University in 2010 using combinations of vinegar,
1081 lemon powder and cherry powder blend. Eight ham treatments were manufactured, processed, sliced and
1082 packaged, and all of the ham treatments contained the base ingredients of ground ham, salt, sugar and
1083 water. Samples were prepared with various treatments: salt, sugar and water; sodium erythorbate,
1084 sodium nitrite and lactate/diacetate blend; a natural nitrate source and a nitrate reducing starter culture
1085 (*Staphylococcus carnosus*); a natural nitrate source, a nitrate reducing starter culture (*Staphylococcus carnosus*)
1086 and an antimicrobial (vinegar, lemon powder and cherry powder blend); a natural nitrate source, a nitrate
1087 reducing starter culture (*Staphylococcus carnosus*) and another antimicrobial (cultured corn sugar and
1088 vinegar blend); a natural source of nitrite without additional antimicrobials; a natural nitrite source and
1089 an antimicrobial (vinegar, lemon powder and cherry powder blend); and a natural nitrite source and
1090 another antimicrobial (cultured corn sugar and vinegar blend) (Niebuhr, et al. 2010).
1091

1092 According to the research, the addition of the antimicrobials appeared to improve control of *L.*
1093 *monocytogenes*, but these products demonstrated a slight variation of inhibitory activity, suggesting that
1094 other inhibitory factors are involved. The treatments with a natural nitrate source and starter culture
1095 had the highest residual nitrite, followed by traditionally cured samples. Residual nitrite declined with
1096 time. The samples with the vinegar, lemon powder and cherry powder blend had the highest pH,
1097 followed by those with a natural nitrite source and no antimicrobials. Traditionally cured samples had
1098 the lowest pH. Ham with the direct addition of sodium nitrite (control) had the lightest color of the
1099 cured samples, and the treatments with the vinegar, lemon powder and cherry powder blend were the
1100 darkest. Traditionally cured samples had the reddest color, followed by those with a natural nitrate
1101 sources and starter culture. These were said to be related to the residual nitrite level found in the product.
1102 No differences were found in the water activity, salt, protein, fat or moisture (Niebuhr, et al. 2010).
1103

1104 Essential Oils:

1105 Campos, et al. (2011) looked at the effectiveness of essential oils in controlling *L. monocytogenes*. The results
1106 of these studies were promising; however, in many instances, combinations of additives or preservative
1107 treatments worked best because the efficacy of the antimicrobials can be influenced by the chemical
1108 composition and the physical conditions of various foods.
1109

1110 Essential oils (EOs) are oily liquid mixes of volatile and complex compounds that are extracted from
1111 different parts of aromatic plants. They are synthesized by plants as secondary metabolites and can be
1112 obtained mainly by steam distillation or super critical fluid extraction. Essential oils can contain 20-60
1113 components, depending on the material they come from and the extraction method used. Terpenes and
1114 terpenoids make up the majority group, and aromatic and aliphatic compounds of low molecular weight,
1115 the minority.
1116

1117 Campos, et al. (2011) examined EOs for their activity against *Listeria* growth in laboratory media, and it was
1118 found that EOs of bay, coriander, cinnamon, clove, licorice, nutmeg, pepper, oregano, winter savory, spruce
1119 and thyme showed the highest inhibitory activity. The effectiveness of oils of basil, lemon balm, marjoram,
1120 mastic tree, rosemary and sage were lower than those mentioned above, whereas *Listeria* showed high
1121 resistance to EOs of aniseed, caraway, fennel, garlic, ginger, onion and parsley.
1122

1123 According to the research, the antimicrobial activity of EOs mainly depends on their composition; however,
1124 the mechanism of antimicrobial action of EOs is not well known. Inhibitory actions are more related to the
1125 main than the minor components. The main components often consist of: carvacrol, thymol, linalool,
1126 eugenol, trans-cinnamaldehyde, p-cymene, 1,8-cineole (eucalyptol) and γ -terpinene. However, the minor
1127 components can modulate the antimicrobial action of the main components, because the research suggests

1128 that several components of EOs are involved in the fixation on cell walls and cellular distribution. It's
 1129 reported that EO components may degrade the cell wall, damage the cytoplasmic membrane and proteins of
 1130 the membrane, leak vital intracellular compounds, coagulate cytoplasm and deplete the proton motive force,
 1131 and that EOs also interact with one another, potentially leading to synergistic antimicrobial effects between
 1132 various oils. For example, Campos, et al. (2011) observed that the growth of *L. monocytogenes* was suppressed
 1133 more when a combination of oils was used (oils of oregano and rosemary; oils of basil, rosemary or sage; and
 1134 oils of rosemary and licorice) than when these oils were used alone.
 1135

1136 Further results in various samples suggested that EOs have lower activity in foods with high fat content.
 1137 This may be due to: (i) EO dissolution in the lipid fraction of the food, decreasing the concentration in the
 1138 aqueous phase, together with antimicrobial action; (ii) the reduced water content in foods, particularly in
 1139 fatty foods, in relation to culture media, which may slow down the movement of the preservative to the
 1140 active site in the microbial cell; and (iii) the presence of fat in the food which may produce a protective layer
 1141 around the bacteria (Campos, et al. 2011).
 1142

1143 Storage temperature, pH, physical structure of food, fat, protein, sugar content, and sensory properties all
 1144 need to be taken into account when considering whether EOs will be effective for controlling pathogens. It
 1145 was reported that chicken frankfurters treated with 2%v/w of clove oil were unacceptable to the
 1146 consumer, whereas samples with 1% were accepted. The latter level had effective antilisterial activity in
 1147 the food. It was found that combining EOs would allow the use of lower levels to reduce *Listeria*
 1148 growth, minimizing the unacceptable sensory changes in the food. Indirect uses of EOs, for example in
 1149 water to wash vegetables similar to the use of chlorine, or in the impregnation of porous surface of
 1150 wood in cheese ripening to improve sanitary safety, are also being considered.
 1151

1152 According to the 2013 list of certified USDA organic operations (USDA 2013), the following agricultural
 1153 products, which are identified above as natural antimicrobials for meat applications, are produced
 1154 organically:
 1155

1156 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

1157
 1158 Sebranek (2007) warned that while agricultural and/or natural antimicrobials may be effective in one way,
 1159 they may be ineffective in another, and stresses staying open to further research in order to ensure that food
 1160 safety of these materials is properly assessed. The research suggests that:

- 1161 1. Acidulants such as vinegar have the potential to accelerate nitrite reactions because of the impact of
 1162 pH. Reducing pH in these products is also a concern for reduced moisture retention, because
 1163 phosphates and many of the traditional water binders cannot be used for natural or organic
 1164 products.
- 1165 2. Cherry powder is high in ascorbic acid, which functions as a strong nitrite reducer but does not have
 1166 as great an impact on pH.

- 1167 3. Natural antioxidants such as rosemary may be used to provide flavor protection and to retard lipid
1168 oxidation in processed meats. However, these compounds do not contribute directly to nitrate/
1169 nitrite reactions in meat systems.
- 1170 4. Liquid sources of naturally occurring nitrates (vegetable juices) also pose some manufacturing
1171 issues. Typically, most of these liquids are not shelf-stable, and are supplied in frozen form. Second,
1172 the added water that is a component of the juices must be considered (Sebranek 2007).
1173

1174 Multi-barrier Preservation Systems:

1175 Apostolidis, Kwon, & Shetty (2008) studied the efficiency of water soluble phenolic extracts of oregano and
1176 cranberry in combination with sodium lactate for control of *L. monocytogenes*. In both broth and cooked meat
1177 studies, the results indicated that the combination of water soluble extracts of oregano and cranberry, at a
1178 ratio of 50:50 and a concentration of 750 ppm, with 2% sodium lactate had the best inhibitory effect in the
1179 tested strain (Apostolidis, Kwon and Shetty 2008).
1180

1181 A similar study looked at the efficacy of three natural antimicrobial ingredients, a 1.5 % vinegar-lemon-
1182 cherry powder blend, a 2.5 % buffered vinegar, and a 3.0 % cultured sugar-vinegar blend, on 14 ham and
1183 turkey samples prepared with various methods of preservation and inoculated with *L. monocytogenes*. While
1184 it was found that the addition of either vinegar-lemon-cherry powder blend or buffered vinegar delayed *L.*
1185 *monocytogenes* growth for an additional 2 weeks, the addition of cultured sugar-vinegar blend delayed
1186 growth for an additional 4 weeks for both ham and turkey. The greatest *L. monocytogenes* delay was observed
1187 in roast beef containing any of the three antimicrobial ingredients, with no growth detected through 12
1188 weeks at 4°C for any of the treatments. *L. monocytogenes* grew substantially faster in products stored at 7°C
1189 than at 4°C. These data suggest that antimicrobial ingredients from a natural source can enhance the safety
1190 of RTE meat and poultry products, but their efficacy is improved in products containing nitrite and with
1191 lower moisture and pH (McDonnell, Glass and Sindelar 2013).
1192

1193 While current research suggests that natural plant extracts can be effective in controlling pathogens in meat
1194 products, the most favorable results tend to result from multiple-barrier food preservation systems, which
1195 use combinations of agricultural and/or natural antimicrobials and sodium or potassium lactate (or other
1196 synthetic antimicrobial ingredients). However, decreasing the shelf life of a product in order to
1197 accommodate the strict use of natural antimicrobials is another option.
1198

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