National Organic Standards Board
Handling Subcommittee
Petitioned Material Proposal
Sodium Lactate and Potassium Lactate
August 25, 2015

Summary of Proposed Action: To add Sodium Lactate and Potassium Lactate to the National List under section §205.605(b). This request was made to the National Organic Standards Board to take under consideration by the National Organic Program, in a memorandum dated June 25, 2014. The original joint petition was submitted on January 5, 2004.

History

On January 5, 2004 the NOP received a combined petition for two substances to be added to the National List for use in organic handling, these substances were Sodium Lactate and Potassium Lactate (the salts of lactic acid). Lactic acid is listed on the National List at §205.605(a) as an approved non-synthetic material for use in products labeled as "organic" or "made with organic (specified ingredients of food group(s)). Lactic acid appears in "Acids (Alginic; Citric – produced by microbial fermentation of carbohydrate substances; and Lactic)".

On January 22, 2004, the NOP notified the petitioner that their petition would not be necessary since the materials (sodium hydroxide, lactic acid, and/or potassium hydroxide), that these two substances were formulated using, were already included on the National List. Eventually, this interpretation was deemed to not be consistent with previous NOSB recommendations on the classification of materials and was causing some confusion within the organic industry regarding the status of the two materials (Sodium lactate and potassium lactate) as well as other lactate salts (example: calcium lactate)(McEvoy 2014). Thus, the NOSB (Handling Sub-committee) took up the request for the consideration for inclusion to the National List, for sodium lactate and potassium lactate on §205.605 (b) Synthetics Allowed.

The original 2004 petition was submitted for the following use: Both sodium lactate and potassium lactate are used in meat processing as a pathogen inhibitor that is added to meat as an ingredient for use in controlling *Listeria monocytogenes* in Ready-to-Eat meat and poultry products. Both of these materials have been recognized by the USDA-FSIS (Food Safety and Inspection Service) as being two of the few known antimicrobials validated through scientific studies to inhibit the growth of *Listeria monocytogenes*, *E.coli*, Salmonella, and other pathogens. They also control *Clostridium Botulinum* (botulism) in meats, as well. Sodium and potassium lactate can replace nitrates/nitrates in meat products and are generally recognized as safe (GRAS).

In the February 17th, 2015 Technical Evaluation Report it mentions that both sodium and potassium lactate are affirmed as GRAS. Sodium lactate is affirmed GRAS at 21 CFR 184.1768 and Potassium Lactate at 21 CFR 184.1639. However, the FDA does not authorize their use in infant foods and formulas.

Sodium lactate and potassium lactate come as a liquid and may be added to meat as an ingredient at the rate of 1% to 4.8% as prescribed by the USDA-FSIS regulations, depending on the product. Whether a handling operation uses sodium lactate or potassium lactate is at the discretion of the processor or by the requirements of the specific recipe – i.e. low sodium products (Applegate Farms 2004).

Manufacture:
Lactic acid is produced from the fermentation of natural food sources such as dextrose (from corn) and sucrose (from sugarcane or sugar beets) or starch. This substrate is fermented by food grade micro-organisms to form lactic acid. Sodium hydroxide (NaOH) is produced by the electrolysis of a concentrated sodium chloride (table salt) solution. Potassium hydroxide (KOH) is a synthetic, inorganic compound produced by an electrolysis process using only potassium chloride (approved for use in organic foods per §205.605(a)) and water.

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

Lactates are naturally produced in the human body.

Discussion:
The original petition asked that sodium and potassium lactate be added to the National List, for use in meat processing as a pathogen inhibitor. While the petitioned request for these materials covered a very specific usage, it is not completely clear whether or not the intended use is currently the only way that these two materials are being utilized in organic handling. This is part of the confusion from the action taken in 2004 by the NOP's decision to not accept the need for the petitioner's request to have sodium lactate and potassium lactate added to the National List.

There does not appear to be any human health concerns associated with either of these two materials according to the information provided in the Technical Evaluation Report. Both materials are considered to be GRAS by the FDA according to this same report. There was an environmental issue raised about the amount of gypsum created in the manufacturing of lactic acid. This concern seems to have been mitigated by utilizing this by-product material (gypsum) as a soil additive (Gypsoil and ADM 2011) and by research being implemented to look at other ways to produce lactic acid. According to a report published by the EPA lactic acid and its salts are readily biodegradable and have low potential to persist in the environment (Environmental Protection Agency 2008).

In the Technical Evaluation Report from February 17, 2015 it does state that no additional ingredients (e.g., stabilizers, preservatives, carriers, anti-caking agents, or other materials) are added to the commercially available forms of these materials. Thus, it would stand to reason that there are no ancillary substances associated with either of these two materials. However, the TR does mention that sodium diacetate (below 2%) sometimes may be combined with either of these two materials to help lower the pH of the surface meat products and therefore decrease microbial growth. Sodium diacetate is GRAS, contains 60% sodium acetate and 40% acetic acid (Miller 2010).

Both sodium lactate and potassium lactate have been allowed for use in organic handling since the January 22, 2004 decision was rendered by the National Organic Program (McEvoy 2014). This decision (to not require a petition for sodium and potassium lactate for inclusion to the National List) was originally based on the fact that all three of the materials used to produce sodium lactate and potassium lactate were already approved and on the National List. That decision was not consistent with previous NOSB Recommendations on classification of materials. The intent of this proposal is to correct that previous decision and go through the appropriate process (Petitioned Material Proposal) to see whether or not these two materials should in fact be added to the National List of Allowed Substances. It is the intent of the subcommittee and ultimately that of the entire National Organic Standards Board by moving forward with this proposal we can clear up the confusion, re-establish a concise and transparent process by which these two materials shall be reviewed and ultimately voted on.

Sodium Lactate
There are three mechanisms by which sodium lactate can have an antimicrobial affect. The first is by changing water activity (it lowers the water activity of meat and thereby slows microbial growth). The second occurs as sodium lactate passes through the cell membrane and lowers intracellular pH. The third takes place as sodium lactate affects cellular metabolism by inhibiting ATP generation (ATP- adenosine triphosphate, a nucleoside triphosphate which transports chemical energy within cells for metabolism (Biology Online 2010)). The lactic acid portion of sodium lactate has antimicrobial properties, as it can be incorporated into the microbial cell. The lactic acid then interferes or slows down the normal metabolic process that generates cell energy in the cell. (Miller 2010).

Potassium Lactate
Potassium lactate has a potassium ion rather than the sodium ion found in sodium lactate. It has been shown to decrease microbial growth and to limit the growth of some major meat pathogens with similar capabilities to those of sodium lactate. Potassium lactate can be used as a substitute for sodium lactate as a non-meat ingredient, with similar functionality, but does not have the salty taste (Miller 2010).

Again, the original petitioned use for these materials was for use in Ready-to-Eat meat and poultry products as an ingredient to function as a pathogen inhibitor, especially for use in controlling *Listeria monocytogenes*.

It should be noted that in the TR it states that meat products that contain sodium and potassium lactates can no longer be labeled as "natural" without a case-by-case assessment of what function these materials are serving in the product, and at what levels (USDA FSIS 2005).

It would assist the NOSB in our consideration of these two petitioned materials if the appropriate organic stakeholders and/or certifiers could provide any additional information regarding the extent that these two materials are being used. Furthermore, are there any additional ways that these materials are currently being used other than the original petitioned use that we should be aware of? Finally, between sodium lactate and potassium lactate is one more commonly used than the other?

Evaluation Criteria (see attached checklist for criteria in each category)

	Criteria Satisfied?		
1. Impact on Humans and Environment	☒ Yes	☐ No	☐ N/A
2. Essential & Availability Criteria	☒ Yes	☐ No	☐ N/A
3. Compatibility & Consistency	☒ Yes	☐ No	☐ N/A
4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for §205.606)	☐ Yes	☐ No	☒ N/A

Substance Fails Criteria Category: NA

Subcommittee Action & Vote:

Classification Motion:
Motion to classify both Sodium Lactate and Potassium Lactate as synthetic.
Motion by: Harold V. Austin IV
Seconded by: Ashley Swaffar
Yes: 7 No: 0 Absent: 0 Abstain: 0 Recuse: 0
Listing Motion:

Motion to list Sodium Lactate and Potassium Lactate on section 205.605(b) with the following annotation: for use as an antimicrobial agent only.
Motion by: Harold V. Austin IV
Seconded by: Ashley Swaffar
Yes: 4 No: 1 Abstain: 2 Absent: 0 Recuse: 0

Approved by Tom Chapman, Subcommittee Chair, to transmit to NOSB August 25, 2015

NOSB Evaluation Criteria for Substances Added To the National List - Handling

Category 1. Adverse impacts on humans or the environment? Sodium and Potassium Lactate

Question	Yes	No	N/A	
1. Are there adverse effects on the environment, or is there a probability of environmental contamination during use or misuse of the substance? [§205.600(b)(2), [§6518(m)(3)]		X		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 its 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). February 17, 2015 TR Lines: 770-774.
2. Are there adverse effects on the environment or is there a probability of environmental contamination during manufacture or disposal of the substance? [§6518(m)(3)]	X			During the fermentation process to make lactic acid, the pH is stabilized by adding calcium carbonate (lime) which neutralizes the acid and results in the formation of calcium lactate. A by-product of the purification process of the calcium lactate during the production of lactic acid is insoluble calcium sulfate (gypsum). In the TR (Feb. 17, 2015) lines782-784 states about gypsum: 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. Lines 792-794 states: 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). Lines 800-802 states that: another commercial manufacturer, Corbin (Purac): 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.

3. Are there any adverse impacts on biodiversity? (§205.200)		X		
4. Does the substance contain inerts classified by EPA as 'inerts of toxicological concern'? [§6517 (c)(1)(B)(ii)]		X		
5. Is there undesirable persistence or concentration of the material or breakdown products in the environment? [§6518(m)(2)]		X		According to the February 17, 2015 TR, lactic acid and its 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).
6. Are there any harmful effects on human health from the main substance or the ancillary substances that may be added to it? [§6517(c))(1)(A)(i); 6517 (c)(2)(A)(i); §6518(m)(4), 205.600(b)(3)]		X		In the TR (February 17,2015) lines 815-817 states: Lactates have been reported to have low oral toxicity, with a lack of adverse effects in feeding studies in which up to 3,900 mg/kg body weight/day was administered to rats for 2 years. Likewise, lactates were proven to be non-genotoxic and non-mutagenic (Purac 2008). TR lines 828-830, As described in other sections of this report, the use of lactic acid and its sodium and potassium salts in certain food applications may reduce risk of foodborne pathogens because of their antimicrobial properties. However, the FDA does not authorize its (sodium or potassium lactate) use in infant foods and formulas.
7. Is the substance, and any ancillary substances, GRAS when used according to FDA's good manufacturing practices? [§205.600(b)(5)]	X			Sodium Lactate is affirmed as GRAS at 21 CFR 184.1768 for use in food with no limitation other than current good manufacturing practice. (Feb. 17, 2015 TR Lines: 203-204) Potassium Lactate is affirmed as GRAS at 21 CFR 184.1639 for use in food with no limitation other than current good manufacturing practice. (Feb. 17, 2015 TR Lines 209-210) In the TR Lines 204 and 210 it states (pertaining to the GRAS statements for these two lactates) However, the FDA does not authorize their use in infant foods and formulas.
8. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 (b)(5)]		X		

Category 2. Is the Substance Essential for Organic Production? Sodium and Potassium Lactate

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Is the substance agricultural? [§6502(1)]		X		
2. Is the substance formulated or manufactured by a chemical process? [§6502(21)]	X			See answer below for Cat. 2, question 3 and 4.
3. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [§6502(21)]	X			According to the TR (Lines 612-615) Sodium lactate and potassium lactate are produced by combining non-synthetic lactic acid and sodium hydroxide or potassium hydroxide, respectively.
4. Is the substance created by naturally occurring biological processes? [§6502(21)]		X		According to the TR (Lines 601-602) Lactic acid, produced from fermentation, is currently listed on the National List, 205.605(a) as a non-synthetic material with no restrictions on use. However, to form either sodium lactate or potassium lactate either sodium hydroxide or potassium hydroxide is added, which both of these materials are on the National List as synthetics allowed.
5. Is there a natural source of the substance? [§ 205.600(b)(1)]		X		TR line 615-616 states "There does not appear from the literature to be a non-synthetic version of sodium lactate or potassium lactate.
6. Is there an organic substitute? [§205.600(b)(1)]	X			TR lines 1,042-1,043 says "research into the use of **natural antimicrobials** in organic and natural meat products is being done with promising results. Research is also being done to look at **agricultural antimicrobial alternatives** such as: cranberry, cherry, lime and vinegar powders. Lines 1,092-1094 states: According to the research, the addition of the antimicrobials appeared to improve control of *L.monocytogenes,* but these products demonstrated a slight variation of inhibitory activity, suggesting that other inhibitory factors are involved. **Essential Oils** (oily mixes of volatile and complex compounds that are extracted from different parts of aromatic plants) are also under going research as possible alternatives as an antimicrobial. **Multi-barrier Preservation Systems** is another potential alternative, which uses multiple substances

				to give control of *L. monocytogenes*.
7. Is the substance essential for handling of organically produced agricultural products? [§205.600(b)(6)]	X			TR (Feb. 17,2015) Lines 913-917 states: There is concern that organic meat products could potentially pose a food safety hazard if they do not contain antimicrobials that are comparable to formulated sodium nitrate ($NaNO_2$) in concentrations known to be highly effective in inhibiting the growth of many food borne pathogens such as *Listeria monocytogenes* (Niebuhr, et al.2010) However, more research into natural antimicrobials in organic and natural meat products is being done with promising results.
8. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]	X			Sodium nitrate is commonly used in curing non-organic meat and poultry products, except for bacon. Vinegar, essential oils and vegetable and fruit juice powders are possible natural/agricultural alternatives that researchers are currently looking at. Campops, et al. (2011) TR lines 936-938 , looked at the effectiveness of organic acids in controlling *L. monocytogenes*. The results of these studies were promising; Lactic Acid cultures also can be used for dry sausage and ham. Bacteriophages (micro-organisms) are utilized as an antimicrobial to control bacteria during the production of foods on the farm, on perishable foods post-harvest, and during food processing. Bacteriophage products are typically sprayed directly on food products prior to packaging (GRN 468; GRN 218; (OMRI 2014b)). TR 984 & 985.
9. Are there any alternative substances? [§6518(m)(6)]	X			Lactic Acid Cultures can be used for dry sausage and ham. Bacteriophages (micro-organisms) are utilized as an antimicrobial to control bacteria and control the growth of pathogens such as *Listeria monocyogenes, Salmonella, and Campyloabacter jejuni* in refrigerated foods (TR 983-984) also phage preparations are sprayed onto the surface of RTE meat and poultry products. According to the product data information for LISTEX™ product, phages are considered processing aids and do not have to be declared on the finished product label (Micreos B.V. 2012). This is a different situation from sodium lactate and potassium lactate, which are

				added to meat as ingredients at the rate of 1% to 4.8% as prescribed by USDA-FSIS regulations, depending on the product (Applegate Farms 2004). TR lines 1011-1015.
10. Is there another practice (in farming or handling) that would make the substance unnecessary? [§6518(m)(6)]	X			The TR mentions 3 possible alternatives listed in the USDA – FSIS, Listeria Rule for Ready-To-Eat products. (Lines 853 – 870) discusses these alternatives: (1) a post-lethality treatment and the use of an antimicrobial agent (either of the lactates could be used for this). Example: deli or hotdog products that are steam pasteurized after packaging and have lactates added in the formulation. (2) either a post-lethality treatment or an antimicrobial agent, or antimicrobial process is applied. Under this alternative, sodium lactate and potassium lactate could be used or the post-lethality treatment or the antimicrobial process. Example: a hotdog or deli product that is treated with a post pasteurization treatment after packaging, such as a steam treatment, and does not contain lactates or any antimicrobial agents. And (3) none of the other options are applied and instead the establishment relies on its sanitation program to control Lm. Example: refrigerated chicken nuggets that are not treated with a post lethality treatment or antimicrobials. Additional verification testing requirements for establishments that produced deli or hotdog products are enforced. (Lethality step: defined as cooking or another process such as fermentation or drying that results in a product that is safe for human consumption without further preparation. (USDA FSIS 2012).
11. Have the ancillary substances associated with the primary substance been reviewed? Describe, along with any proposed limitations.	x			

Category 3. Is the substance compatible with organic handling practices? Sodium and Potassium Lactate

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Is the substance consistent with organic handling? [§6517(c)(1)(A)(iii); 6517(c)(2)(A)(ii)]	X			Materials (both sodium lactate and potassium lactate) have been allowed for use in organic handling, but are now needing to be petitioned for inclusion to the National List, due to the Memo from the NOP to the NOSB dated June 25th, 2014.
2. Is the manner of the substance's use, manufacture, and disposal compatible with organic handling? [§205.600(b)(2)]	X			
3. Is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]	X			
4. Are the ancillary substances reviewed compatible with organic handling [?			X	
5. Is the nutritional quality of the food maintained with the substance? [§205.600(b)(3)]		X		
6. Is the primary use as a preservative? [§205.600(b)(4)]	X			In the original petition from Purac America & Trumark Co.'s in 2004, both sodium lactate and potassium lactate were petitioned for use in organic meat processing as a pathogen inhibitor. In the TR (Lines 670 – 671) it states: " One of the primary uses of sodium lactate and potassium lactate is as a preservative in meat. As stated above, sodium (and potassium) lactate has the ability to extend shelf-life of meat products. The petitioner stated that their targeted use of these two materials was as a pathogen inhibitor primarily to control *Listeria monocytogenes*.
7. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law)? [§205.600(b)(4)]		X		TR (lines 721-723) says: Similar to lactate acid, sodium and potassium lactates do not recreate or replace flavors, colors, textures, or nutritive values lost in processing, but are often used to improve or enhance flavors and textures of food products, especially meat. Sodium lactate is known to enhance meat flavor due to the salty taste that it provides, potassium lactate offers similar attributes but is less salty. Sodium lactate results in enhanced overall flavor and beef flavor intensity (TR line 729-730).

Category 4. Is the commercial supply of an organic agricultural substance fragile or potentially unavailable? [§6610, 6518, 6519, §205.2, § 205.105(d), §205.600(c)] **Sodium and Potassium Lactate**

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Is the comparative description as to why the non-organic form of the material /substance is necessary for use in organic handling provided?	X			
2. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **form** to fulfill an essential function in a system of organic handling?	X			
3. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **quality** to fulfill an essential function in a system of organic handling?			X	
4. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **quantity** to fulfill an essential function in a system of organic handling?			X	
5. Does the industry information about unavailability include (but is not limited to) the following? a. Regions of production (including factors such as climate and number of regions);			X	
b. Number of suppliers and amount produced;			X	
c. Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies;			X	
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or			X	
e. Other issues which may present a challenge to a consistent supply?			X	