

Formal Recommendation
From: National Organic Standards Board (NOSB)
To: the National Organic Program (NOP)

Date: April 27, 2016

Subject: Addition of Sodium Lactate and Potassium Lactate at §205.605(b) - Synthetics allowed.

NOSB Chair: Tracy Favre

The NOSB hereby recommends to the NOP the following:

Rulemaking Action: X

Guidance Statement:

Other:

Statement of the Recommendation:

The NOSB classified both sodium lactate and potassium lactate as synthetic, and recommended addition to the National List at §205.605(b) Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s))” Synthetics Allowed. Sodium lactate and Potassium lactate as annotated: “for use as an antimicrobial agent and pH regulator only”.

Rationale Supporting Recommendation (including consistency with OFPA and Organic Regulations):

The NOP received a petition to add these two materials to the National List on January 5, 2004. It was decided at that time that this would not be necessary since the three materials (sodium hydroxide, potassium hydroxide, and lactic acid) used to formulate these two products were already on the National List. On June 25th, 2014 the NOP issued a memorandum to the National Organic Standards Board asking them to once again take up this original petition and review these two materials as petitioned for consideration to be added to the National List. The previous decision by the NOP had resulted in considerable confusion and the NOP felt that a new review was needed for the benefit of organic certifiers and handlers.

Since sodium lactate and potassium lactate (along with the three materials that they are derived from) are currently being used in organic handling, they were deemed by the NOSB to be compatible with organic handling principals. Discussions around how these materials were being used by handlers showed that the uses had expanded from the original petitioned use and, thus, there was a need for an annotation. This annotation not only helped to cover the current use pattern, but also helped to restrict any future uses to those currently in use by organic handlers. Further discussions also included consideration of the uses of these materials for controlling pathogens (such as *Listeria monocytogenes*, *E.coli*, *Salmonella*, and other pathogens) from a human health perspective (as opposed to viewing these materials as preservatives).

Both potassium lactate and sodium lactate, along with the materials that they are made from, have all been looked at through various reviews to see that they meet the appropriate criteria. They did not show any negative impact on human or environmental health. They do appear to be essential under their current use patterns in organic handling, since they have been in use for a number of years already and these uses have expanded from the original petitioned use. Also, sodium and potassium lactate do

seem to fit into the compatibility criteria quite easily. Currently for some uses there does not appear to be any alternatives that give the organic handlers the same level of functionality and control as either of these two lactates give them.

NOSB Vote:

Classification Motion: Move to classify both sodium lactate and potassium lactate as synthetic.

Motion by: Harold V. Austin IV

Seconded by: Ashley Swaffar

Yes: 15 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Listing Motion: Move to list sodium lactate and potassium lactate at §205.605(b) of the National List with the following annotation: for use as an antimicrobial agent and pH regulator only.

Motion by: Harold V. Austin IV

Seconded by: Tom Chapman

Yes: 12 No: 1 Abstain: 2 Absent: 0 Recuse: 0

Motion Passed

National Organic Standards Board
Handling Subcommittee
Petitioned Material Proposal - Sodium Lactate and Potassium Lactate
February 23, 2016

Summary of Proposed Action: To add Sodium Lactate and Potassium Lactate to the National List at §205.605(b). NOP requested in a memorandum dated June 25, 2014 that the National Organic Standards Board review these materials. The original joint petition was submitted January 5, 2005, by Christopher Ely, Applegate Farms, on behalf of the manufacturers Purac America and Trumark Company.

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 and potassium lactate were composed of substances that were already included on the National List (sodium hydroxide, lactic acid, and/or potassium hydroxide). Eventually, this interpretation was deemed inconsistent 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 Subcommittee) took up the request for the consideration of sodium lactate and potassium lactate for inclusion to the National List, §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/nitrites 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 microorganisms to form Lactic acid. Sodium hydroxide 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:

This proposal was referred back to the Handling Subcommittee at the fall 2015 NOSB meeting in Stowe, VT. The reason for doing so was to provide the subcommittee and board an opportunity to look into the other ways that these two materials were currently being used by organic handlers. This was based off of information provided to the full board during the public comment period.

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 was not completely clear whether or not the petitioned 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.

Information provided during the written public comment period prior to and at the fall NOSB meeting in Stowe, Vermont by several commenters mentioned other ways that these materials were being used. . Some of those additional uses are: use in organic meat flavors (e.g. chicken flavor, beef flavor) and use in organic processed meats (e.g. sausages, meatballs, etc.). These are a few of the uses mentioned by one certifier about how some of their clients currently use these materials. Also, in comments provided both in written comments submitted and in oral testimony by an international certified organic handler, they have used sodium lactate in the manufacturing of their organic herb and spice pastes for 5 years prior to the NOP memo. It has become an integral part of their production process. They have tried other materials but so far sodium lactate provides the functional part of what they need and ask for it to be allowed for not only antimicrobial control, but also as a pH regulator. Sodium lactate helps them to maintain a balanced pH of their product, which is a critical parameter for both safety and product quality (Chang et al, 2008; Nguetack et al, 2009; Canillac et al, 2004; Gurierrez et al, 2008) (9/30/2015 Public Comment document: Botanical Food Company pg4). Some comments provided that the inclusion of these two materials onto the National List would help to eliminate the confusion that currently exists.

There were some comments opposed to the listing of both materials, stating that they should not be allowed in organic processing further stating that they were intended for use as preservatives. It should also be noted that in the February 17th, 2015 Technical Evaluation Report, it states that: meat products that contain sodium or potassium lactate 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).

There are alternatives mentioned in the TR and the original petition such as: natural antimicrobials and agricultural antimicrobials (such as cranberry, cherry, lime and vinegar powders) (both currently being researched), essential oils, lactic acids, and bacteriophages (microorganisms) to name a few.

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) (Feb.17, 2015 TR) 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) (Feb.17, 2015 TR).

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, there are no ancillary substances associated with either of these two materials. However, the TER 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) (Feb.17, 2015 TR). During the public discussion at the Stowe, Vermont NOSB meeting (Fall 2015) it was decided that sodium diacetate is an additional active ingredient sometimes used in conventional processing to enhance the microbial control measures and did not serve as an ancillary substance for this petitioned use as it applies to organic handling.

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 have sodium and potassium lactate petitioned 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) (Feb.17, 2015 TR).

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) (Feb.17, 2015 TR).

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 providing microbial control of *Listeria monocytogenes*.

Information provided from public comments for the fall 2015 NOSB meeting made it clear that while both forms (sodium and potassium) lactate are used, sodium lactate seemed to be the one more commonly used. The rationale between the differences in use is primarily due to whether or not the use was for a sodium or a low sodium product. Also, as stated information provided by public comment and subcommittee, research does show that these two substances are currently used in organic handling in a variety of ways for several different uses other than just the original petitioned use.

Recently the original petitioner (formerly Purac and now Corbion Purac) contacted the NOP stating that they had just become aware that these two substances were back up for discussion. They were asked to submit their comments during the up-coming open public comment period in writing or during oral testimony. This helps to address one of the concerns from the Handling Subcommittee that if these materials were important in organic handling, then why hadn't they heard from the petitioner or manufacturer. It was just brought to their attention.

Please provide the full NOSB your comments on this proposal and if you are an organic handler currently using either of these materials (or have used them prior to the NOP memo), if the proposed annotation would capture your current use pattern, assuming these two materials were added to the National List. Also, could you explain why these substances would be preferred over currently used alternative materials or practices?

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

	Criteria Satisfied?		
1. Impact on Humans and Environment	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2. Essential & Availability Criteria	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
3. Compatibility & Consistency	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for §205.606)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> N/A

Subcommittee Action & Vote:

Classification Motion: Move to classify both sodium lactate and potassium lactate as synthetic.

Motion by: Harold V. Austin IV

Seconded by: Ashley Swaffar

Yes: 6 No: 0 Abstain: 0 Absent: 2 Recuse: 0

Listing Motion: Move to list Sodium Lactate and Potassium Lactate at §205.605(b) of the National List with the following annotation: for use as an antimicrobial agent and pH regulator only.

Motion by: Harold V. Austin IV

Seconded by: Tom Chapman

Yes: 5 No: 0 Abstain: 1 Absent: 2 Recuse: 0

Proposed Annotation (if any): for use as an antimicrobial agent and pH regulator only.

Basis for annotation: To meet criteria above Other regulatory criteria Citation

Notes: To regulate how each of these substances are to be allowed for use in organic handling or processing.

Approved by Harold Austin, Handling Subcommittee Chair, to transmit to NOSB February 23, 2016