

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

Date: April 2015

Subject: Petition to add Zinc Sulfate at §205.603(b)

NOSB Chair: Jean Richardson

The NOSB hereby recommends to the NOP the following:

Rulemaking Action: X

Guidance Statement:

Other:

Statement of the Recommendation (Motion #1):

Motion to classify zinc sulfate as synthetic, passed

Statement of the Recommendation (Motion #2):

Motion to list zinc sulfate at §205.603(b) for use in hoof and foot treatments only, passed

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

The addition of Zinc Sulfate to the National List provides livestock producers with a tool to treat foot disease in livestock, and thereby ensuring the welfare of the animals. Further, with the addition of Zinc Sulfate, it is likely that the use of Copper Sulfate for treating of foot diseases will be decreased. The buildup of persistent copper in agricultural soils is a serious issue. While Zinc Sulfate can also accumulate in soils, its persistence is less certain due to the mode of attachment to soils. Zinc Sulfate is therefore considered a more benign material compared to Copper Sulfate. OFPA Criteria: Essentiality

Committee Vote:

Motion to classify zinc sulfate as synthetic

Motion by: Tracy Favre

Seconded by: Jean Richardson

Yes: 14 No: 2 Abstain: 0 Absent: 1 Recusal: 0

Motion passed

Motion to list zinc sulfate at §205.603(b) for use in hoof and foot treatments only

Motion by: Tracy Favre

Seconded by: Calvin Walker

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

Motion passed

**National Organic Standards Board
Crops or Livestock Subcommittee
Petitioned Material Proposal
Zinc Sulfate
February 24, 2015**

Summary of Proposed Action:

A petition has been received to allow zinc sulfate to be used as a footbath for control of foot rot in livestock, particularly dairy cattle, sheep and goats. Zinc, a trace element, is necessary for all living organisms. It plays a role in many cell regulatory processes, including the innate immune response. Commercially, zinc sulfate is manufactured from zinc ore mined from underground or open pit mines. Zinc ore deposits are spread widely throughout the world. Zinc ores are extracted in more than 50 countries. China, Australia, Peru, Europe and Canada are the biggest zinc mining countries. Zinc sulfate is most commonly produced by the interaction of zinc salts and sulfuric acid.

Foot rot is a contagious disease. Temperature and moisture play an important role in the transmission and invasion of the bacteria that causes the disease. Most outbreaks occur in seasons with high rainfall, warm temperatures and lush pasture growth. Infectious material may be transferred directly from the soil to animals.

Foot rot is a significant cause of lameness in sheep, goats and cattle caused by the interaction of three bacterial species. Since the first identification of foot rot in sheep, cattle and goats several substances have been used for treatment with varying degrees of efficacy including ethanol, copper sulfate, formalin, and other materials. They vary in side effects and cost. However, most of the substances that are used are not included in the National List. Copper sulfate and zinc sulfate are two of the most accepted treatments and are comparable in efficacy. Zinc sulfate has proven particularly effective at controlling the bacteria associated with foot rot, and is sometimes used in combination with other materials, including copper sulfate. The combination of zinc sulfate with sodium lauryl sulfate (as an excipient) has proven to be more effective than zinc sulfate with copper sulfate. Aspirin (Salicylic Acid) is allowed for use in organic livestock production for health care use to reduce inflammation. Salicylic acid has also been shown to be effective in treatment of foot rot in dairy cattle. A combination of Australian Tea Tree Oil, Jojoba oil, Benzathonium Chloride, water, propylene glycol and emulsifiers (Hoofmate™) as a topical application has been used with some success in treating foot rot (Schivera, 2014). Literature mentions that peracetic acid and hydrogen peroxide foams are also used in the treatment and control of foot rot, although the efficacy of these treatments is controversial.

Spent footbath liquids are typically discarded in the on-farm lagoon system and/or washed out with manure. Water from lagoons is then applied to agricultural lands, leading to concerns regarding the accumulation of the footbath active ingredients in soils. The potential for the accumulation of copper in the environment has led to serious concerns about continued use of copper sulfate as an ingredient in footbaths. Zinc sulfate has the potential to accumulate in the soil, but the bioavailability levels of zinc are dependent upon a number of factors including soil pH, soil aggregates and moisture levels, and therefore it is difficult to determine what level of zinc in soils would be considered toxic. Unlike copper contamination, excess zinc can be successfully removed from soil by planting sunflower and canola.

Request for public comment:

The Livestock subcommittee seeks input from the public regarding the effectiveness of alternative methods for controlling foot rot, including management practices, and the use of hydrogen peroxide, peracetic acid or other materials. Further, the subcommittee seeks feedback on whether the availability of zinc sulfate for use in organic livestock production would likely reduce the use of copper sulfate for treatment of foot rot.

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

	Criteria Satisfied?		
	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
1. Impact on Humans and Environment	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2. Essential & Availability Criteria	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
3. Compatibility & Consistency	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A

Substance Fails Criteria Category: [] Comments:

Subcommittee Action & Vote

Classification Motion: Move to classify zinc sulfate as synthetic

Motion by: Tracy Favre

Seconded by: Jean Richardson

Yes: 7 No: 0 Absent: 1 Abstain: # Recuse: #

Listing Motion: Move to list zinc sulfate for use as a footbath only, at §205.603(b) of the National List,

Motion by: Tracy Favre

Seconded by: Calvin Walker

Yes: 4 No: 3 Absent: 1 Abstain: 0 Recuse: 0

Proposed Annotation (if any): For use as a footbath only

Basis for annotation: X To meet criteria above

Approved by Tracy Favre, Subcommittee Chair, to transmit to NOSB February 24, 2015

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

Category 1. Adverse impacts on humans or the environment? Substance: Zinc Sulfate

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is there a probability of environmental contamination during use or misuse? [§6518(m)(3)]	X	X		Zinc sulfate has a particular mode of action in soils which makes it very difficult to assess regarding contamination levels. Soil pH, soil composition, moisture and other factors all affect the amount of bioavailability of zinc.
2. Is there a probability of environmental contamination during, manufacture or disposal? [§6518(m)(3)]	X	X		Using good manufacturing practice, the likelihood of contamination from manufacture is unlikely. However, some less developed countries are less likely to have environmental controls on the manufacturing process.
3. Are there any adverse impacts on biodiversity? (§205.200)	X	X		Perhaps. See comments #1 above. High levels of zinc in the soil could have negative impact on soil organisms.
4. Does the substance contain inerts classified by EPA as 'inerts of toxicological concern'? [§6517 (c)(1)(B)(ii)]		X		Zinc Sulfate is considered an inert, not listed as one of toxicological concern. It is also considered as GRAS by FDA and is used as a nutritional supplement.
5. Is there potential for detrimental chemical interaction with other materials used in organic farming systems? [§6518(m)(1)]	X			Can bind with other metals (particularly copper compounds) to form compounds less likely to degrade in soils.
6. Is there a toxic or other adverse action of the material or its breakdown products? [§6518(m)(2)]	X	X		In some cases, and depending upon soil pH and other characteristics, zinc can change forms into those that are more persistent in the environment.
7. Is there persistence or concentration of the material or breakdown products in the environment? [§6518(m)(2)]	X	X		Yes, but again, depends upon soil conditions.
8. Would the use of the substance be harmful to human health or the environment? [§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)]		X		Zinc is actually an essential nutrient. It is unlikely that there would be the possibility of high levels of zinc affecting human health, given its petitioned use.
9. Are there adverse biological and chemical interactions in the agro-ecosystem? [§6518(m)(5)]	X	X		Unclear what the levels of zinc are that would be detrimental to the environment. Some soil microorganisms have the ability to adapt to higher zinc levels.

10. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518(m)(5)]				Perhaps. Difficult to determine because of the way zinc interacts with the soil. Zinc sulfate foot bath water is typically discarded in the farm lagoon system with the water later applied to the agricultural land. A buildup of zinc in the soils could be the result.
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Category 2. Is the Substance Essential for Organic Production? Substance: Zinc Sulfate

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is the substance agricultural? [§6502(1)]	X			Mineral mined and then refined and purified.
2. Is the substance formulated or manufactured by a chemical process? [§6502(21)]	X			Produced using either high heat of an acid agent to create Zinc sulfide compound.
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			Mined or reclaimed from zinc ore.
4. Is the substance created by naturally occurring biological processes? [§6502(21)]		X		
5. Is there a natural source of the substance? [§ 205.600(b)(1)]		X		Zinc salts do exist but produced using sulfuric acid.
6. Is there an organic substitute? [§205.600(b)(1)]		X		Mineral source
7. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]		X		
8. Are there any alternative substances? [§6518(m)(6)]	X			Copper sulfate, hydrogen peroxide and other materials can be used as foot baths to eradicate foot rot, but in some cases are not as effective, and in the case of sheep, can be toxic.
9. Are there other practices that would make the substance unnecessary? [§6518(m)(6)]	X	X		Hoof trimming, dry flooring and isolation of infected animals can help control foot rot. However, the infection can become increasing debilitating to the animal as it progresses, and can be difficult to control without proper treatment.

Category 3. Is the substance compatible with organic production practices?

Substance: Zinc Sulfate

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is the substance consistent with organic farming and handling? [§6517(c)(1)(A)(iii); 6517(c)(2)(A)(ii)]	X	X		If used after other management practices are put in place, it can be effective means of controlling an infectious disease in cattle, sheep and goats. But there are some drawbacks to using this material, including the potential for buildup of zinc in agricultural soils when lagoon water is applied to the land.
2. Is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]				
3. If used in livestock feed or pet food, is the nutritional quality of the food maintained with the substance? [§205.600(b)(3)]		X		
4. If used in livestock feed or pet food, is the primary use as a preservative? [§205.600(b)(4)]		X		Zinc sulfate is allowed as a feed supplement, but in this case is being petitioned for foot bath.
5. If used in livestock feed or pet food, is the primary use to recreate or improve flavors, colors, textures, or nutritive value lost in processing (except when required by law)? [§205.600(b)(4)]		X		
6. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: [§6517(c)(1)(B)(i); copper and sulfur compounds toxins derived from bacteria pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals livestock parasiticides and medicines production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers	X	X		Zinc interacting with sulfuric acid to create zinc sulfate.