




Comments to the National Organic Standards Board

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CORNUCOPIA
INSTITUTE

The Cornucopia Institute is engaged in research and educational activities supporting the ecological principles and economic wisdom underlying sustainable and organic agriculture. Through research and investigations on agricultural and food issues, The Cornucopia Institute provides needed information to family farmers, consumers, stakeholders involved in the good food movement, and the media.

The Cornucopia Institute wishes to thank the thousands of family farmers and their "urban allies" who fund our work with their generous donations.

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CONTENTS

INTRODUCTION

The Cornucopia Institute is pleased to offer the National Organic Standards Board our formal analysis of and recommendations on materials up for review at the Fall 2015 meeting.

Cornucopia adamantly believes that a thorough and appropriate review process needs to take place for all petitioned materials and that all materials should conform with the Organic Foods Production Act of 1990 (OFPA) and the federal organic standards. We hope that the Board will benefit from Cornucopia's independent perspective in these comments.

The Cornucopia Institute is a 501(c)(3) public interest farm and food policy research organization. Cornucopia engages in educational activities supporting the ecological principles and economic wisdom underlying sustainable and organic agriculture.

Through research and investigations on agricultural and food issues, The Cornucopia Institute provides educational information to farmers, consumers, other stakeholders involved in the good food movement, and the media.

We are proud to represent over 10,000 supporting members, including an impressive percentage of the nation's certified organic farmers.

We do not sell materials seeking approval or sunset reauthorization, and we do not sell organic products that utilize any substances that might be petitioned.

We have no financial interest in the approval of any of the materials proposed for use in organic foods.

These formal comments follow the Fall 2015 Tentative Agenda released by the USDA National Organic Program, beginning with materials under review by the Crops Subcommittee and concluding with those under review by the Livestock Subcommittee.

Likewise, each subcommittee section follows the Tentative Agenda, beginning with 2017 Sunset Materials, followed by Petitioned Materials Proposals.

CROPS SUBCOMMITTEE

2017 SUNSET MATERIALS

Copper Sulfate & Fixed Copper Products

SUMMARY

The Cornucopia Institute supports the relisting of synthetic copper sulfate and fixed copper products, as "restricted use" materials, scheduled to sunset in 2017, provided that they are used in a manner that minimizes copper accumulation in the soil **with an added annotation** stating**: user needs to document multiple alternative attempts to control target including the adoption of high crop diversity in the field.**

We also recommend that the Crops Subcommittee further investigate the particular uses of copper products in plant disease control to determine when they are necessary and **should utilize that data to propose an annotation for specific uses and rates.** Finally, we recommend setting a five-year average maximum application rate for all copper products.

Rationale:

- **The use of copper products as fungicides should NOT be considered before adequate soil and cultural management practices are employed.**
- Numerous viable disease prevention **alternatives exist**, including crop rotation, highly diverse plantings, lower plant density, intercropping, companion planting, sanitation practices, planting buffer strips and cover crops, applying biological control organisms, compost, and natural and synthetic horticultural oils.
- Application of copper is a **routine** disease control practice in organic tomato production in the eastern United States. **Applications are recommended weekly, resulting in as many as 12 applications per growing season**.[1]
- The broad-spectrum nature of copper materials as disease control agents **can harm natural and released biological control agents** contributing to the "pesticide treadmill" that organic practices are designed to avoid.
- There are non-copper materials that are effective as fungicides, including aqueous potassium silicate, ammonium carbonate, sulfur, and hydrogen peroxide; these must be considered first, even though some plant diseases do not respond as well to them as to copper.[2]
- Situations may exist where prevention methods are not effective. In these cases, **copper may need to be used after less toxic materials have been trialed**.

[1] http://www.agrisk.umn.edu/cache/arl01501.pdf
[2] https://www.extension.purdue.edu/extmedia/bp/bp-69-w.pdf

- There are soil types that are copper deficient and require copper supplementation.

DISCUSSION

Copper products are **synthetic substances** allowed for use (with restrictions) in organic crop production as described below:

- For plant disease control provided they are used in a manner that minimizes copper accumulation in the soil. Fixed copper materials cannot be used as herbicides.
- In aquatic rice systems, as an algicide and insecticide (to control tadpole shrimp). Use is limited to one application per field during any 24-month period. Application rates are limited to levels which do not increase baseline soil test values for copper over a timeframe agreed upon by the producer and accredited certifying agent.[3]

When copper sulfate and fixed copper products are used in agriculture, they eventually dissociate to form positively charged copper **particles that persist and accumulate in the environment**.[4]

Copper sulfate is exempt from any EPA tolerance level requirements when it is applied as a fungicide on crops or on raw agricultural commodities after harvest. This exemption also applies when copper sulfate is used as an algicide or herbicide in irrigation systems or bodies of water where fish or shellfish are cultivated.[5]

Fixed coppers, allowed for plant disease control for organic crop production, are also "copper products that are exempt from tolerance by the EPA." This includes Bordeaux mixture, basic copper carbonate (malachite), copper-ethylenediamine complex, copper hydroxide, copper-lime mixtures, copper linoleate, copper oleate, copper oxychloride, copper octanoate, copper sulfate basic, copper sulfate pentahydrate, cupric oxide, and cuprous oxide. These materials "must be used in a manner that minimizes accumulation in the soil and shall not be used as herbicides."[6]

In 2009, the EPA required revised labels on copper products to define maximum single application rates for each crop and the maximum amount of copper that can be applied each year. It was required that labels include advice on how to limit spray drift during application. The goals were to reduce the potential for introducing more copper into ecosystems than was necessary and to limit the exposure to non-target organisms.[7]

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[3] http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=79c4ebcacc3e33f160e0024456ef889f&n=pt40.24.180&r=PART&ty=HTML#se40.24.180_11021

[4] http://www.epa.gov/oppsrrd1/reregistration/REDs/copper_red_amend.pdf

[5] http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=79c4ebcacc3e33f160e0024456ef889f&n=pt40.24.180&r=PART&ty=HTML#se40.24.180_11021

[6] http://www.epa.gov/oppsrrd1/reregistration/REDs/copper_red_amend.pdf

[7] http://www.epa.gov/oppsrrd1/reregistration/REDs/copper_red_amend.pdf

Ethylene Gas – 2017 Sunset

SUMMARY

The Cornucopia Institute **opposes** the relisting of ethylene gas at §205.601(k), to regulate flowering of pineapples.

Rationale:

- The use of ethylene gas, a synthetic growth regulator, is incompatible with organic production. Ethylene is made from natural gas liquids or crude oil, is toxic to humans, plants, and animals at high doses, and poses dangers as an explosive gas.
- **The supplemental TR from 2011 is substandard and includes unanswered questions**, specifically how ethylene gas is applied and how its use can be applicable to smaller operations.
- Uniform flowering is not essential for growing certified organic pineapples.

DISCUSSION

Ethylene gas is **used for forced induction of flowering in pineapples**. Regulation of the flowering increases crop production and creates a year-round supply of fresh pineapple. Ethylene is given off naturally by the ripening fruit. When ethylene gas is sprayed on pineapple plants, chemical changes occur that stimulate the release of ethylene, leading to **unnatural** flowering and fruiting. Other substances commonly used for pineapple growth regulation, but not listed for organic production, are acetylene, calcium carbide and ethephon.[8]

According to the 2011 TR, ethylene gas is injected into pressurized water and applied via boom sprayers in large pineapple operations. Application takes place 7 to 15 months after planting. Smaller operations are less likely to use this method due to the cost of the needed equipment. This inequity creates a market advantage for large-scale organic pineapple operations, which are able to produce the fruit throughout the year. As one reviewer stated in the 2009 TAP report, "**It appears the ethylene use in pineapples is more a question of economics and farm size rather than agronomic need**."[9]

Past NOSB deliberations

In March 2011, the Crops Subcommittee initially issued a recommendation against the relisting of ethylene gas for pineapple flowering induction. The members of the committee expressed **concerns about alignment with organic farming principles**, the necessity to

[8] http://www.scielo.br/scielo.php?pid=S0006-87052005000400001&script=sci_arttext
[9] http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5067073

achieve higher yields through year-round production, and the benefit to large-scale operations as opposed to smaller organic farms.[10]

In April 2011 the Crops Subcommittee met again "to consider new public comments and determined that the utility of alternatives may not be sufficient for the needs of the industry as a whole and reconsidered their prior recommendation." The NOSB then rejected the previous recommendation and ethylene continued to be allowed for use by organic farmers to induce pineapple flowering.

The 2015 Crops Subcommittee's review concluded: "While it would appear that there is not a functionally viable alternative for ethylene gas, especially for the larger producers, it is concerning that there was no more support for this material via the public comment period (both written and oral), by those that have supported it in the past, especially from the producers themselves."

The subcommittee motion to remove ethylene gas from the National List based on compatibility in OFPA and/or 7 CFR §205.600(b) was Yes: 4 No: 0 Abstain: 1 Absent: Recuse: 0.

Technical Report

For the current sunset review period, the NOSB requested additional information on items that were addressed but unanswered in the 2011 Supplemental Technical Report. Specifically, these were:

1. What are the current application methods used for application of ethylene gas, for both large and small-scale production?
2. What alternative organic methods or practices have been investigated during the current sunset cycle?
3. Were there alternative ethylene gas application methods that would make handling the material more feasible for small-scale production.

The comments received did not help answer these questions and the current sunset review cannot be properly vetted without this information.

Note: The Organic Foods Production Act of 1990 explicitly gives the NOSB the power to secure Technical Reviews to assist in reviewing materials. It is legally incumbent upon the NOP to fulfill this and other requests for TRs from the board. An updated TR answering the above questions is needed to properly review this material.

Alternatives exist

Alternatives to ethylene gas exist. Application of calcium carbide has been used in conventional pineapple production, but this material has not been petitioned for organic production. **The calcium carbide method may be less expensive and more available to**

[10] http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5089523

small-scale operations. Cold-stress forced flowering is an organic method that has shown to be effective. **Ice-cold water or ice crystals** applied 3-4 times stimulated production of ethylene and induced flowering when nighttime temperatures reached 25 degrees or less.[11,12]

According to the 2011 TR, the use of the cold-stress method is not common and further research was needed at that time. A review of the literature found no indication of increased use of cold-stress induction of flowering. This is not surprising, considering the availability of ethylene gas for organic production.

Another natural alternative is the use of smoke from burning organic materials to promote ethylene release, a method discovered in the late 1800's when growers in the Azores used smoke for flower induction.[13] This cultural flower induction method is still practiced in the Azores, with seasonal variation of time to flowering. However, the use of smoke may present environmental and health concerns.

Environmental concerns

Ethylene gas is highly flammable and an air pollutant. As a volatile organic compound, ethylene contributes to ground level ozone. However, the overall impact of the use of ethylene gas in pineapple production is unlikely to harm the crops or the environment.[14]

Human health concerns

Ethylene gas is volatile and highly flammable. Farm workers must be trained in safety handling procedures to prevent explosions. Additionally, precautions must be taken to avoid inhalation of the gas. Exposure to high levels of ethylene oxide in the air may lead to seizures and cataracts in people. Irritation of the eyes and nose as well as hand/eye coordination problems may result from low-level exposure.[15]

CONCLUSION

The Cornucopia Institute **opposes** the relisting of the 2017 sunset material ethylene gas at §205.601(k), to regulate flowering of pineapples. Ethylene gas is hazardous to humans and the environment, is not essential for organic production, and is incompatible with organic production as a synthetic growth regulator. It is certainly possible that, if grown using truly organic methodology, pineapple might be available only on a seasonal basis, in the U.S., rather than the extended marketing window made possible through the use of off-farm inputs derived from natural gas or petroleum-based compounds.

[11] http://link.springer.com/article/10.1007/s10725-009-9421-9;
[12] http://www.actahort.org/books/902/902_37.htm;
[13] http://www.ishs-horticulture.org/workinggroups/pineapple/PineNews20.pdf
[14] http://apps.sepa.org.uk/spripa/Pages/SubstanceInformation.aspx?pid=54
[15] http://www.atsdr.cdc.gov/PHS/PHS.asp?id=732&tid=133

Humic Acids – 2017 Sunset

SUMMARY

The Cornucopia Institute **is neutral** on the relisting of humic acids as synthetic substances allowed for use as plant and soil amendments.[16] Humic acids are currently listed for use when they are "naturally occurring deposits, water and alkali extracts only."[17] Synthetic humic acids are frequently derived from coal products. Given the potential environmental and human health effects associated with coal mining, The Cornucopia Institute **recommends that a new Technical Report be prepared to fully review and discuss these concerns before the relisting proceeds.**

Humic acids are commonly used as soil supplements in agriculture and may be considered essential for organic crop production by some growers. The Cornucopia Institute recommends that **a new Technical Report review and discuss the sources of humic acid currently utilized in organic agriculture and whether any alternative sources are viable options.**

The relisting for humic acids should include an **annotation requiring that humic acids used in organic crop production come from sources with a low potential for environmental and human harm, based on the findings of a new Technical Report.**

Rationale:

- Humic acids are an important component of organic agriculture because they increase nutrient availability, the ability of soil to retain water, and help root penetration, although there are specific production practices that provide humic acids without the need for synthetic sources.
- **The 2006 Technical Report did not fully explore the environmental and human health effects of coal mining, which is a precursor activity for humic acid extraction.**
- Alternative materials that have the same effect as humic acids, or other sources of humic acids that come from environmentally sound practices, need further investigation prior to relisting.

DISCUSSION

Humic acids are commonly used as a soil supplement in agriculture. Humic acids are not considered a fertilizer because they do not directly provide nutrients to plants. Instead, humic acids increase the availability of nutrients necessary for plant growth. Humic acids are negatively charged and attract positively charged nutrients, making them available for

[16] 7 CFR 205.601(j)

[17] 7 CFR 205.601(j)(3) Humic acids—naturally occurring deposits, water and alkali extracts only.

plant uptake.[18] Humic acids are also used in organic agriculture to increase the water retention capability of soil and to help with root penetration.[19]

Studies show that humic acids increase plant height, leaf area, shoot and root dry weight.[20] The beneficial effects of humic acids have "relatively large responses at low application rates."[21]

In nature, humic acids are found in manure, peat, lignite coal, and leonardite.[22] Leonardite, an oxidized form of lignite coal, is the most concentrated source of humic acids and the most widely used raw material for their extraction.[23] Leonardite is plentiful and inexpensive compared to other possible humic acid sources. The extraction process that is allowed in organic agriculture uses alkali solutions (potassium and ammonium hydroxide) to remove the humic acids from coal. [24]

An exemption for a prohibited substance in organic production and handling operations should be allowed only if:

- It is not harmful to human health or the environment;
- It is necessary to the production or handling of the agricultural product, because of the unavailability of wholly natural substitutes; and
- It is consistent with organic farming and handling.[25]

It is unclear whether humic acids meet these National List guidelines for exemptions.

Technical Report

The 2006 TR was <u>deficient</u>; it did not fully discuss and review the environmental and human health impacts, or the availability of substitutes or alternative sources of

[18] Senn, T.L., A.R. Kingman, and W.C. Godley. A review of humus and humic acids. Clemson University Horticulture Department, Research Series No. 165. Available Online at: http://andersonshumates.com/wp-content/uploads/2012/09/A-Review-of-Humus-and-Humic-Acids.pdf. Last Accessed: October 1, 2015.

[19] Humic & Fulvic Acids: The Black Gold of Agriculture? Available at: http://www.humintech.com/pdf/humicfulvicacids.pdf

[20] R.M. Atiyeh, S. Lee, C.A. Edwards, N.Q. Arancon, J.D. Metzger. The influence of humic acids derived from earthworm-processed organic wastes on plant growth. *Bioresource Technology*, Volume 84, Issue 1, August 2002, Pages 7–14. *Available at:* http://www.sciencedirect.com/science/article/pii/S0960852402000172

[21] *Arancon, Norman Q.; Edwards, Clive. A.; Lee, Stephen; Byrne, Robert (2006).* Effects of humic acids from vermicomposts on plant growth *(PDF). European Journal of Soil Biology 42: S65.* doi*:10.1016/j.ejsobi.2006.06.004. Available at:* http://www.biosci.ohio-tate.edu/~soilecol/Full%20articles/2006/Effects%20of%20humic%20acids.pdf

[22] Tan, K.H. 2003. Humic matter in soil and the environment: principles and controversies, CRC Press, Section 2.2.4, page 26. Ebook available at: https://books.google.co.uk/books?id=nDLcBQAAQBAJ&dq=leonardite+humic+acid+extractable&lr=

[23] Senn, T.L., A.R. Kingman, and W.C. Godley. A review of humus and humic acids. Clemson University Horticulture Department, Research Series No. 165. Available Online at: http://andersonshumates.com/wp-content/uploads/2012/09/A-Review-of-Humus-and-Humic-Acids.pdf. Last Accessed: October 1, 2015.

[24] Kline, S.W and C.E.Wilson. 1994. Proposal for experimentation with Arkansas lignite to identify organic soil supplements suitable to regional agricultural needs. Available online at: http://www.humintech.com/001/articles/article_arkansas_tech_univeristy.html. Last Accessed: October 1, 2015.

[25] 7 U.S.C. 6517(c)(1) National List – Guidelines for prohibitions or exemptions

humic acids. In addition, the initial 1996 TAP reviewers were William Zimmer (who checked that he had a commercial interest in this material), James A. Johnson, and Paul Sachs, who was affiliated with North Country Organics at the time and did not disclose that he also had a commercial interest in humic acids. Specifically, the initial 1996 TAP report and 2006 TR correctly identify that most commercial humic acids are derived from lignite coal <u>without</u> discussing the impacts of coal mining.

Another related Technical Report was prepared in 2012 by The Organic Center for the USDA National Organic Program regarding oxidized lignite/humic acid derivatives. [26] This report was prepared in response to a petition requesting that hydrogen peroxide be allowed in the manufacture of synthetic humic acids.[27] While this document mentions environmental and human health concerns that were not considered in the 2006 TR, the nature of the petition means the impacts were not considered in relation to the material's continued presence on the National List. Like the 2006 TR, the 2012 TR does not discuss the practicality of replacing synthetic humic acids with wholly natural alternatives.

A new Technical Report should be prepared for acids to fully explore the full range of environmental and human health harms associated with lignite coal mining.
Both the 2006 TAP and 2012 Technical Report lack in-depth discussion and review of alternatives to humic acids**.** The effects of crop rotation, tilling, cover crops, compost amendments, and general long-term soil management should be discussed as viable natural alternatives to synthetic humic acid amendment.

IFC Consulting, an IFC International company[28], compiled the 2006 Technical Report. IFC does not share their client lists and has been implicated as **having serious conflicts of interest** in the past.[29] **The identities of the scientists who authored this report are being withheld from the public**. It is vital that the public have access to information including the scientists' credentials and any institutional affiliations. Any new Technical Report must contain reliable information and should therefore come from a source without conflicts of interest or the suspicion inherent bias.

The effects of humic acids on human health

Humic acids may stimulate the immune system which may increase the symptoms of existing auto-immune diseases.[30] In that case, the humic acids must be ingested, which is a low risk for people applying organic compounds to their crops.

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[26] http://www.ams.usda.gov/sites/default/files/media/Ox%20lig%20Technical%20Evaluation%20Report%20%282012%29.pdf
[27] http://www.ams.usda.gov/sites/default/files/media/Ox%20lig%20NOSB%20Subcommittee%20Proposal.pdf
[28] http://www.icfi.com/
[29] News articles regarding IFC's work: http://www.motherjones.com/environment/2014/03/icf-international-contractor-evaluated-keystone-report-state-department-conflict-interest-transcanada *and* http://the.honoluluadvertiser.com/article/2005/Jan/22/bz/bz01p.html
[30] Humic Acid. http://www.webmd.com/vitamins-supplements/ingredientmono-1129-humic%20acid.aspx?activeingredientid=1129&activeingredientname=humic%20acid

Humic acids, when combined with or present in treated drinking water, can react with the chemicals used in the chlorination process to form byproducts.[31] These byproducts are considered "disinfectants," which are toxic to humans. The main threat to human health from these byproducts in an organic setting is from agricultural land runoff.[32]

Exposure to coal mine dust causes various respiratory diseases in workers.[33] Though the number of miners has decreased with mechanization, using equipment to mine creates more dust hazards for existing workers. The most common result of dust inhalation is *coal worker's pneumoconiosis*.[34] Coal mining also poses risks to worker health from blasting and from the use of oversized equipment for earth moving and extraction.[35]

Another serious human health concern is *Balkan endemic nephropathy*, an irreversible kidney disease.[36] Though precise etiology is still unknown, the disease is positively correlated with living near open lignite mines. It is believed that as the coal weathers, it leeches into the water supply of nearby populations.[37] Miners are at higher risk since they are more likely to ingest the coal while working. Balkan endemic nephropathy leads to renal failure and death.

Alternatives may exist

The Cornucopia Institute believes that the 2006 Technical Report and the related 2012 Technical Report are deficient in their discussion of alternatives. The Technical Reports also failed to discuss the viability of different sources of humic acids.

Humic acids are abundant in nature. Any source of biological material will supply some amount of humic acids to a crop. For example, composts and mulches composed of manures and yard waste contain humic acids which can be applied to the soil as an

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[31] *Chemistry and Toxicity of Disinfection.* Drinking Water and Health: Disinfectants and Disinfectant By-Products: Volume 7. National Research Council (US), Safe Drinking Water Committee. Washington (DC): National Academies Press (US); 1987. *Available at:* http://www.ncbi.nlm.nih.gov/books/NBK218000/

[32] *Chemistry and Toxicity of Disinfection.* Drinking Water and Health: Disinfectants and Disinfectant By-Products: Volume 7. National Research Council (US), Safe Drinking Water Committee. Washington (DC): National Academies Press (US); 1987. *Available at:* http://www.ncbi.nlm.nih.gov/books/NBK218000/

[33] Coal Mine Dust Exposures and Associated Health Outcomes (2011). United States Centers for Disease Control and Prevention. *Available at:* http://www.cdc.gov/niosh/docs/2011-172/pdfs/2011-172.pdf

[34] M. H. Ross, and J. Murray. *Occupational respiratory disease in mining*. Occupational Medicine 2004; 54: 304–310. doi:10.1093/occmed/kqh073. *Available at:* http://occmed.oxfordjournals.org/content/54/5/304.full.pdf

[35] Coal: Construction and Mining Impacts, United States Department of the Interior. Washington, D.C.: Office of Indian Energy and Economic Development, Tribal Energy and Environmental Information Clearinghouse (TEEIC). Retrieved October 1, 2015. *Available at:* http://teeic.indianaffairs.gov/er/coal/impact/construct/index.htm

[36] Feder GL, Radovanović Z, & Finkelman RB. *Relationship between weathered coal deposits and the etiology of Balkan endemic nephropathy*. Kidney Int Suppl. 1991 Nov;34:S9-11. *Available at:* http://www.ncbi.nlm.nih.gov/pubmed/1762344

[37] Gluhovschi G, Modalca M, Mărgineanu F, Velciov S, Gluhovschi C, Bob F, Petrica L, Bozdog G, Trandafirescu V, Gădălean F. *Epidemiological data regarding Balkan endemic nephropathy in relationship with the Pliocene coal etiological hypothesis*. Rom J Intern Med. 2011;49(1):11-24. *Available at:* http://www.ncbi.nlm.nih.gov/pubmed/22026248

alternative to synthetic hummus amendments.[38] Other alternative farming methods boost nutrient uptake in crops. Some of these alternatives include rotating crops and planting cover crops to boost nutrient availability. All of these long-term soil-building techniques may provide the same benefits as those derived from synthetic humic acids.

These practices are already encouraged as part of an OSP and, if done properly, may or may not meet the need for humic acid amendments. If thoughtful soil management can take the place of the "quick and dirty" sourcing of lignite coal as a hummus source, then holistic soil management should be favored. **The viability of these alternatives in different soil types needs to be investigated further before relisting.**

Environmental concerns

The primary environmental concern associated with humic acids is related to the extraction of coal. While other sources of humic acids are available, leonardite (oxidized lignite coal) remains the most concentrated source found in nature.

Surface coal mining is associated with potential environmental harm.[39] Common effects of coal mining are: eliminating vegetation and disrupting the soil profile, displacing wildlife and habitat, and permanently changing the topography of the area mined. The noise associated with mining will also displace and disrupt the natural behaviors of surrounding wildlife. Waste generated from surface mining includes scrap rock and coal refuse. Groundwater and surface water contamination, typically from acid drainage or soil erosion, is a possibility wherever coal is mined. Chemicals can also be released into the water when soils exposed by mining activity are weathered.

Water is also used in coal mining operations and may come from natural ground and surface sources near the mine.[40] The diversion of water can impact freshwater habitat and even drinking water availability.

All of these environmental dangers associated with surface coal mining can be minimized by strict management. Rehabilitation of mines after coal extraction can help return the preexisting ecosystems to a natural state. Careful management of water resources and waste products is necessary to prevent serious environmental damage.

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[38] Allison Jack, and Janice E Thies. *Compost and Vermicompost as Amendments Promoting Soil Health*. DOI: 10.1201/9781420017113.ch31 In book: Biological Approaches to Sustainable Soil Systems, Publisher: CRC Press, Editors: Norman Uphoff, pp.453-466. *Available at:* http://www.researchgate.net/publication/255702142_Compost_and_Vermicompost_as_Amendments_Promoting_Soil_Health

[39] Coal: Construction and Mining Impacts, United States Department of the Interior. Washington, D.C.: Office of Indian Energy and Economic Development, Tribal Energy and Environmental Information Clearinghouse (TEEIC). Retrieved October 1, 2015. *Available at:* http://teeic.indianaffairs.gov/er/coal/impact/construct/index.htm

[40] Coal: Construction and Mining Impacts, United States Department of the Interior. Washington, D.C.: Office of Indian Energy and Economic Development, Tribal Energy and Environmental Information Clearinghouse (TEEIC). Retrieved October 1, 2015. *Available at:* http://teeic.indianaffairs.gov/er/coal/impact/construct/index.htm

If the coal mined for humic acids is environmentally damaging to a degree that cannot be mitigated by good resource management, humic acids derived from coal sources would not be consistent with good organic farming and handling principles.

Crops Subcommittee action

The subcommittee proposed removal of synthetically extracted humic acids from the National List based on whether the use is compatible with organic agriculture.[41]
The vote in the subcommittee to remove humic acids from §205.601(j)3 was: Yes: 2 No: 2 Abstain: 1 Absent: 0 Recuse: 0

CONCLUSION

The Cornucopia Institute remains **neutral** toward relisting humic acids as a synthetic substance used in organic crop production until more investigation is done to determine whether the current usage of synthetically extracted humic acids meets the Organic Foods Production Act criteria. Many farmers rely on synthetically manufactured humic acids as they are listed, and these materials in general have an essential role in agriculture. However, there may be viable options for humic acids, including other synthetically extracted options that do not have the same environmental and human health considerations.

The Cornucopia Institute strongly **recommends that a new Technical Report be completed before humic acids are considered for relisting under §205.601**. The nine-year-old Technical Report does not adequately review and discuss the potential for environmental and human health damage from lignite coal mining or go into an adequate review of alternative materials. The tangentially related 2012 Technical Report mentions human and environmental impacts without sufficient review.

In addition, a new Technical Report should discuss the availability and environmental impact of humic acids not derived from coal (such as peat and compost sources). It may be that there is no viable alternative to the current synthetically extracted humic acids because of the volume needed to meet organic farmers' current needs.

[41] Organic Foods Production Act (OFPA). 7 CFR 205.600(b)

Lignin Sulfonate – 2017 Sunset and Petition

SUMMARY

The Cornucopia Institute **supports** the petition to remove lignin sulfonate as an allowed synthetic substance to §205.601 (l)(1) as a floating agent in post-harvest handling based on a lack of essentiality. In addition, Cornucopia **does not support the relisting of lignin sulfonate** (2017 Sunset) for use as a dust suppressant, as a chelating agent (7 CFR §205.601(j)(4)), and as a plant or soil amendment.

Other uses not applicable to these comments:

- Calcium lignosulfonate and sodium lignosulfonate may be used as inert ingredients in pesticide products. They are on the EPA's inert ingredients list (List 4B).
- There is a petition for the use of lignin sulfonate in aquatic plant production that is still pending. At the Spring 2014 NOSB meeting, it was referred back to the Livestock Subcommittee until the NOP issues a proposed rule on organic aquaculture standards.
- Lignin sulfonate is recovered from the spent pulping liquids from sulfite pulping (applying heat, pressure, and sulfur dioxide to wood).

Rationale:

- Use of lignin sulfonate as a floatation agent is **non-essential; no organic handler in the U.S. is reported to be using it for this purpose**.
- **Alternative floating agents on the National List** are in use (i.e., sodium carbonate or potassium carbonate).
- Lignin sulfonate **should be removed for use as a dust suppressant and plant or soil amendment because there are safer alternatives** to increasing organic matter in soil and preventing erosion that do not result in the same risks for high biological oxygen demand (BOD) in waterways.
- Lignin sulfonate is **produced from paper pulping which entails treating wood chips with sodium hydroxide and sodium sulfide** (white liquor). Byproducts from paper pulping include **dioxins and malodorous air emissions**.

DISCUSSION

Lignin is one of the main components of all vascular plants and the second-most abundant polymer in nature. Lignin sulfonate is recovered from the spent pulping liquids (red or brown liquor) from sulfite pulping (applying heat, pressure, and sulfur dioxide to wood). Ultrafiltration and ion-exchange are used to separate lignosulfonates from the spent pulping liquid.[42]

[42] Lebo, Stuart E. Jr.; Gargulak, Jerry D. and McNally, Timothy J. (2001). Lignin. *Kirk -Othmer Encyclopedia of Chemical Technology*. John Wiley & Sons, Inc.

Lignin sulfonates are negatively charged resulting in interactions with cations to form lignin sulfonate salts, such as sodium lignosulfonate, magnesium lignosulfonate, ammonium lignosulfonate, and calcium lignosulfonate.[43] Calcium lignosulfonate and sodium lignosulfonate may be used as inert ingredients in organic pesticide products (they are on EPA's inert ingredients list, List 4B).

Lignin sulfonate has been used in organic agricultural production as a dust suppressant, a chelating agent for fertilizer applications, and an emulsifier, adjuvant, and stabilizer for pesticide applications. It acts as a dust suppressant due to its large size and affinity for binding with smaller dust compounds forming a heavier complex. When lignin sulfonates come into contact with small soil particles through their use as chelating agents, the soil particles are adsorbed to the lignin sulfonate due to the presence of polar and non-polar areas on the surface of the lignin molecule. These interactions do not result in chemical changes but are limited to a physical binding and adsorption.

Lignin sulfonates **may persist for several months to a year when used for dust suppression before they break down**, depending on rain.[44] Soil binders are a temporary soil stabilization technique. More permanent erosion control measures include wood chips, gravel, and increased vegetation.[45]

The use of lignin sulfonate as a plant or soil amendment and dust suppressant should be removed due to the **risk of contamination of waterways**. When lignin sulfonates erode into waterways, their decomposition removes dissolved oxygen from water, **harming aquatic organisms**.

Lignin sulfonate, for use as a floatation agent, is added to float tanks used to remove pears and stone fruit from bins that are completely submerged in float tanks. Stone fruit has the same density as water so lignin sulfonate can be added to the tank water to increase its specific gravity to help the fruit float. The fruit is then able to float out of the bins, eliminating the need for excessive physical contact with the fruit.

A petition to remove lignin sulfonate from §205.601(l) for use as a floating agent was submitted in November 2014 by the Organic Trade Association. The petition indicates it is non-essential for this purpose and has been replaced with other materials agents (i.e. sodium carbonate or potassium carbonate).

[43] OMRI. 2010. OMRI Brand Name Products List and Generic Materials List, Organic Materials Review Institute. Eugene, Oregon. http://www.omri.org/simple-gml-search/results/lignin.

[44] CPWA. 2005. Dust Control for Unpaved Roads, A Best Practice by the National Guide to Sustainable Municipal Infrastructure. Canadian Public Works Association. http://gmf.fcm.ca/files/Infraguide/Roads_and_Sidewalks/dust_control_unpaved_rd.pdf

[45] http://www.coconino.az.gov/DocumentCenter/View/5481

Environmental concerns

Like all organic matter in water, the primary concern regarding lignin sulfonates is their **high biological oxygen demand** (BOD) upon decomposition in waterways. The process of decomposition by microorganisms removes dissolved oxygen from the water, impacting aquatic organisms. Likewise, when lignin sulfonates are discharged to waterways, their decomposition removes dissolved oxygen from water. The lack of dissolved oxygen can be **harmful to aquatic organisms** if large amounts of lignin sulfonates are discharged into waterways at once. Therefore, lignin sulfonate–treated dump water for fruit processing would need to be processed in a treatment system before its disposal or ideally recycled for other uses.[46] In addition, the use of lignin sulfonate as a dust suppressant, chelating agent, and soil amendment may cause harm to waterways after rain events.

Human health concerns

In addition, lignin sulfonate is a byproduct of the paper milling process, byproducts of which include hydrogen sulfide, methyl mercaptan, dimethyl sulfide, dimethyl disulfide, and other volatile sulfur compounds causing malodorous air emissions and issues with disposal. **The 2011 Technical Review by ICF International (scientists unknown) was deficient in its review of the environmental concerns affiliated with the paper milling industry**. Dioxin is a highly toxic contaminant that is considered a likely human carcinogen (U.S. EPA, 2010c) and is a possible contaminant from the process of paper pulping. In addition, sulfur dioxide, another contaminant, can adversely affect the respiratory system.[47]

Alternatives exist

Alternatives to lignin sulfonate for use as a **floating agent** in post-harvest handling of fruit is potassium carbonate and sodium carbonate, both of which were also found to be effective floating agents by researchers at Oregon State University.[48]

Alternative dust suppressants allowed for use in organic production include non-synthetic (natural) sources of magnesium chloride and calcium chloride.[49] Magnesium chloride from synthetic sources is allowed for use in organic agriculture for dust suppression only if it is derived from seawater. Synthetic calcium chloride is allowed for use only as a livestock feed ingredient or in livestock healthcare, but not for use as a dust

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[46] Raabe, E.W. 1968. Biological Oxygen Demand and Degradation of Lignin in Natural Waters. Journal Water Pollution Control Federation 40:R145-R150. http://www.google.com/url?q=http://www.vliz.be/imisdocs/publications/150320.pdf&sa=U&ei=BFADVar0O8ywogTvlICIDw&ved=0CB8QFjAB&sig2=kn7lifR5-1u3rZfrufgNtQ&usg=AFQjCNHTU2CVFxCle-cbWJzcLAMyL-ghvQ

[47] http://www.ams.usda.gov/sites/default/files/media/Lignin%20Sulfonate%20TR%202011.pdf

[48] Sugar, D. 2002. Pear Flotation Studies, 2001-2002. 2002 Proceedings of the Washington Tree Fruit Postharvest Conference, March 12-13, Yakima, WA. WSU-TFREC Postharvest Information Network. Washington State University, Pullman, WA. http://postharvest.tfrec.wsu.edu/PC2002K.pdf

[49] "Lignins: A Safe Solution for Roads". *Dialogue/Newsletters Vol.1 No. 3*. Lignin Institute. July 1992.

suppressant.[50] Applications of gravel and surface roughening at angles perpendicular to winds, and wood chip mulch or vegetative cover are all good alternatives to lignin sulfonate as a dust suppressant.[51]

Alternatives to use of lignin sulfonate as a soil amendment include cover cropping, crop rotation, companion planting, compost applications, contour planting, no-till or low-till practices, windbreaks, and not tilling when windy. The use of lignin sulfonate as a soil amendment is simply input substitution for good soil management practices.

Alternatives to lignin sulfonate for use as chelating agents in organic agriculture include non-synthetic amino acids and non-synthetic citric acid. In addition to the use of allowed non-synthetic chelates, soil fertility can be managed by promoting naturally occurring chelates in the soil including humates, fulvates, and organic root exudates. Management practices, including no-till farming or organic matter applications, can increase naturally occurring chelates in the soil.[52]

International regulations

The Canadian General Standards Board allows the use of lignin sulfonate as a dust suppressant, formulant ingredient, and chelating agent.[53] The International Federation of Organic Agriculture Movements (IFOAM) includes calcium lignosulfonate on its List of Substances for Organic Production and Processing. No other lignin sulfonates are included.[54] As of 2009, calcium lignosulfonate is allowed by the CODEX Alimentarius Commission as a food additive.[55]

Until 2008, lignin sulfonate was not allowed to be used in the production or handling of certified organic products exported to Japan from the United States. In 2008, the Ministry of Agriculture, Forestry, and Fisheries (MAFF) in Japan lifted the ban on lignin sulfonate used as a dust suppressant or chelating agent in organic crop inputs but maintained the ban on lignin sulfonate used in post-harvest handling (i.e., floatation agent for pears and stone fruit). Products exported to Japan were required to have verification that they were

[50] NOSB. 1995. National Organic Standards Board Materials Database: Lignin Sulfonates. http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5057314

[51] U.S. EPA. 2006. Dust Control Fact Sheet. National Pollutant Discharge Elimination System, US Environmental Protection Agency. Retrieved on January 14, 2011 from http://cfpub.epa.gov/npdes/stormwater/menuofbmps/index.cfm?action=browse&Rbutton=detail&bmp=52

[52] Jones, C. and Jacobsen, J. 2009. Micronutrients: Cycling, Testing and Fertilizer Recommendations. Nutrient 680 Management Module No. 7. From Nutrient Management: a self-study course from MSU Extension 681 Continuing Education Series. Montana State University Cooperative Extension. Publication 4449-7. May 682 2009. Retrieved on January 12, 2011 from http://landresources.montana.edu/nm/Modules/Module7.pdf.

[53] Canadian General Standards Board. 2009. Can/Cgsb-32.311-2006: Organic Production Systems Permitted Substances Lists. http://www.tpsgc-pwgsc.gc.ca/cgsb/on_the_net/organic/032_0311_2006-e.pdf.

[54] IFOAM. 2008. IFOAM Indicative List of Substances for Organic Production and Processing. December 8, 2010 from http://www.ifoam.org/about_ifoam/standards/pdfs/20080423_IFOAM_Indicative_List.pdf.

[55] Codex Alimentarius Commission. 2010. Codex Class Names and the International Numbering System for Food Additives. (CAC-MISC 6-2010). Joint FAO/WHO Expert Committee on Food Additives (JECFA). http://www.fao.org/ag/agn/jecfa-additives/search.html?lang=en.

handled without lignin sulfonate by way of an export certificate and be imported by a JAS-certified importer. The restriction on lignin sulfonate as a handling material for organic products exported to Japan was dropped when the U.S./Japan Equivalency Arrangement went into effect (January 1, 2014).[56]

Lignin sulfonate is not specifically discussed by the European Union Regulations.

Crops Subcommittee discussions

The petition to remove lignin sulfonate for use as a flotation aid was found sufficient and the Crops Subcommittee is not requesting a new TR. **The 2011 TR was compiled by ICF International and does not name the scientists**.

The Crops Subcommittee solicited comments about whether or not lignin sulfonate was essential for use as a flotation aid and none were received.

Motion to remove lignin sulfonate from §205.601(l)(1) for use as a floating agent in post-harvest handling, and to acknowledge support for the petition received on this removal: Yes: 5 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Motion to remove lignin sulfonate from §205.601(j)(4) as chelating agent and dust suppressant: Yes: 0 No: 5 Abstain: 0 Absent: 1 Recuse: 0

CONCLUSION

The Cornucopia Institute **supports** the petition to remove lignin sulfonate as an allowed synthetic substance to §205.601 (l)(1) as a floating agent in post-harvest handling based on a lack of essentiality. In addition, we **do not support the relisting of lignin sulfonate** (2017 Sunset) for use as a dust suppressant, a chelating agent, and a plant or soil amendment because alternative, safer organic soil management practices can be implemented that do not raise the environmental concerns surrounding the contamination of waterways.

[56] USDA. 2009. Global Agriculture Information Network (GAIN) Report. Japan Lifts Two Banned Substances for the U.S. Organic Trade. GAIN Report JA9005, January 16, 2009. Foreign Agricultural Service, US Department of Agriculture. Retrieved from http://www.fas.usda.gov/gainfiles/200901/146327052.pdf.

Liquid Fish Products – 2017 Sunset

SUMMARY

The Cornucopia Institute **supports the relisting of liquid fish products** as synthetic substances allowed for use in organic crop production as a plant and soil amendment.[57] We recommend that the Crops Subcommittee further investigate the issue of overfishing as it relates to this material to **determine whether an annotation regarding sustainable fishery sources would be appropriate**.

An annotation requiring regular testing of liquid fish products for heavy metals should also be implemented and limits set to prevent the accumulation of heavy metals in soils and crop plants. We also recommended that the listing of liquid fish products be revisited in the future, as organic and/or more sustainable sources of fish product become available.

Rationale:

- Liquid fish products are an important plant and soil amendment for many organic farmers, including the widespread use of fish products in greenhouse starts and as foliar sprays that help prevent pests and disease.
- Liquid fish products are utilized in organic farming because they contain fundamental nutrients, including nitrogen, and many critical trace minerals.
- Liquid fish products are likely to contain heavy metals that can accumulate in soil and crop tissue. Regular testing of liquid fish products for heavy metals should be required and limits set.
- Alternative sources exist for fertilizer, but fish products are recommended for their superior bio-availability for crops, ease of application, and relative safety for human handlers.
- Overfishing is a serious concern for all products utilizing native fisheries. Some sources for liquid fish products may not come from regulated fisheries.
- Sourcing fish products from aquaculture operations or from fish waste product is still associated with environmental concerns.
- Forage fish harvest can be associated with grave human rights problems, including slavery and human trafficking, and physical abuses that are not compatible with organic agriculture ideals.

DISCUSSION

Liquid fish products are classified as **synthetic substances** allowed for use in organic crop production as plant or soil amendments. Liquid fish products are considered synthetic because acid is added via chemical processes to stabilize the product and adjust the pH. This alters the natural form of the fish product. The type and amount of acid added to the

[57] 7 CFR 205.601(j)

fish products is regulated.[58] Only sulfuric, citric, or phosphoric acid can be used to adjust the pH to prevent spoilage. After the pH is adjusted the finished fish product is often blended with other ingredients to create the finished product that is then marketed to farmers. Depending on the finished product, other ingredients that may be blended with the fish product include enzymes, amino acids, and plain water.

Technical Report

The 2006 TR is out of date and was incomplete when it was first produced. There is no review of the issues of sustainability that arise from the use of fish products, and no discussion of whether concerns of overfishing can be addressed by a choice of materials. **Material supplied for liquid fish products may come from either wild sources or the aquaculture industry, and the 2006 Technical Report does not review or discuss the potential differences between these material sources.** The Magnuson-Stevens Fishery Conservation and Management Act[59] is the principal law governing marine fisheries in the United States. The 2007 amendments to Magnuson-Stevens, which requires that the National Oceanic and Atmospheric Administration (NOAA) end overfishing, rebuild depleted stocks, and set sustainable catch limits for all the marine fisheries they manage, may have some bearing on the issue of sustainability that could not have been explored in the 2006 TR.

One method used to create liquid fish products includes the fermentation of fish and fish waste by adding a carbohydrate source, along with a starter culture. **There is no review or discussion in the 2006 TR to determine if the addition of a carbohydrate may come from a GMO source, an excluded method with the National Organic Program.**

Some high nitrogen fertilizers, including some liquid fish products, have been highlighted as having **a high potential for fraud through the addition of synthetic nitrogen.** An NOP guidance was issued to help address this issue.[60] **This concern should be addressed in a new TR.**

While the 2006 TR lists alternative natural products, it does not explore the viability of these products as replacements for liquid fish products. A superior alternative to liquid fish products as they stand may not exist, but the Crops Subcommittee should have all the relevant information before moving forward.

The 2006 TR was compiled by ICF Consulting, an IFC International company. *ICF* is an extremely large *consulting* agency that works for industry clients, nonprofits, and

[58] 7 CFR 205.601(j)(7) Liquid fish products—can be pH adjusted with sulfuric, citric or phosphoric acid. The amount of acid used shall not exceed the minimum needed to lower the pH to 3.5.
[59] 16 U.S.C. 1801 et seq. *Magnuson-Stevens Fishery Conservation* and *Management Act.* As Amended January 12, *2007. Available at:* http://www.nmfs.noaa.gov/msa2005/docs/MSA_amended_msa%20_20070112_FINAL.pdf
[60] Guidance: Approval of Liquid Fertilizers for Use in Organic Production. NOP 5012, Effective Date: July 22, 2011. Found at: http://www.ams.usda.gov/sites/default/files/media/5012.pdf

government agencies.[61] However, ICF does not share their client lists and has been implicated as having serious conflicts of interest in the past.[62] It is unclear what ICF's conflicts procedures are. A new TR must be more transparent and should therefore come from a source without proven conflicts of interest.

Essentiality to organic crop production

The use of liquid fish products is widespread among organic farmers as a fertilizer, often as a foliar application or as a soil amendment. Individual liquid fish products differ in their nutrient makeup, but in general these soil and crop amendments provide a good source of nitrogen that is balanced with phosphorus and potassium. Liquid fish products also include a wide range of other micronutrients that promote crop health. The availability of different liquid fish products on the market also allows farmers to choose the nutrient combination that would be most beneficial to their particular crop needs.

The primary benefits of liquid fish products are that these products are highly bio-available to crops and are easy for farmers to apply. In general, liquid fish feeds improve crop yields and plant health and reduce both disease and insect activity in crops. Liquid fish products are often used in organic farming during periods of rapid plant growth when a source of available nitrogen is essential.

A superior alternative to liquid fish products may not exist

Alternatives to liquid fish products providing the same benefits of bio-availability and ease of use with a similar nutrient profile do not currently exist. Specifically, the nutrients derived from fish products are more available to crops than compost or manures and are in a liquid form, making it easy to apply to plant starts and through drip irrigation.

The possible development of USDA certification standards for organic aquaculture products and aquatic species is **currently under review**.[63] Internationally, several certifying bodies have developed organic aquaculture standards that could be utilized for liquid fish products in organic crop applications. **If an organic and sustainable source of fish is available, it should be considered before non-organic fish sources**.

Environmental concerns

The primary environmental concern with liquid fish products, as acknowledged by the Crops Subcommittee, is the problem of sustainability. Long-term sustainability issues arise whenever fish is harvested or grown, because of the possibility of overfishing and the

[61] http://www.icfi.com/

[62] News articles regarding IFCs work: http://www.motherjones.com/environment/2014/03/icf-international-contractor-evaluated-keystone-report-state-department-conflict-interest-transcanada and http://the.honoluluadvertiser.com/article/2005/Jan/22/bz/bz01p.html

[63] https://afsic.nal.usda.gov/aquaculture-and-soilless-farming/aquaculture/organic-aquaculture

environmental impact aquaculture can have on outside systems. Both wild and farmed sources of fish material have an impact on the health of the ocean and marine wildlife.

Harvesting of wild fish removes valuable nutrients from marine ecosystems and may harm sensitive wildlife, including marine mammals, which rely on robust fisheries as food. The environmental effects of aquaculture depend on the techniques being utilized. For example, land-based tank systems are less susceptible to contaminating the outside environment with fish escape, parasites, and fish waste. In contrast, open-ocean fish farms can contribute parasites, fish waste, and chemical loads to the surrounding environment. Most aquaculture also requires the input of a feed source, which may include GMO grains or a source of wild fish meal that may not be sustainably harvested.

It is difficult to trace the source of the original fish materials used in liquid fish fertilizers. Unfortunately, common brands of fish fertilizer note that they use wild-sourced whole-fish products rather fish byproduct (which would consist of the guts, tails, heads, and bones).[64] These brands often claim that their fertilizer is sourced from "waste fish" that have no direct value for human consumption. Unfortunately these "waste fish" consist of forage fish species that play a vital role in ocean ecosystems.

Forage fish and other fish low on the food chain are often harvested for their oils and then the remaining fish is used to formulate the agricultural fish product. When these fish species are depleted it has a catastrophic effect on the ecosystems they inhabit. Predator species, including marine mammals, will experience population crashes when their food supply disappears. Pollution from overgrowth of the algae forage fish consume has been reported when stocks are overfished.[65]

Sometimes liquid fish products are sourced from waste materials, such as byproduct from canneries. While this source is more sustainable in some respects, obtaining fish product from wild or farmed sources always triggers environmental issues that must be addressed in the regulations.

The Magnuson-Stevens Fishery Management and Conservation Act requires that NOAA end overfishing, rebuild depleted stocks, and set sustainable catch limits for all the marine fisheries they manage. NOAA collects data to determine fish stock statuses for United States fisheries and measures fishery performance using their Fish Stock Sustainability Index.[66]

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[64] See, as examples: http://fertilizerbrokerage.com/liquid-fish-5-1-1.html and http://www.natureslawn.com/product/neptunes-harvest-2-4-1-liquid-fish/ and http://www.gsplantfoods.com/liquid-fish.html

[65] Shannon, L., Coll, M., Neira, S., & Cary, P. (2009). Impacts of fishing and climate change explored using trophic models. *Climate change and small pelagic fish*, 158. Available at: http://www.cmima.csic.es/files/webcmima/docs/biblio-pdf/doc_2475.pdf

[66] Fish Stock Sustainability Index, found at http://www.nmfs.noaa.gov/sfa/fisheries_eco/status_of_fisheries/fssi.html

NOAA also provides an annual report on the state of U.S. fisheries. The 2014 report[67] details what sources of fish can be harvested sustainably. These reports only include statistics on fisheries managed by the U.S., but other countries regulate their fisheries in a similar manner. Unregulated fisheries are a bad source for liquid fish products, because there is no way to trace whether a stock is being sustainably harvested.

Runoff from farms utilizing fish products as soil or plant amendments can be a concern, because excess nitrogen or other minerals in water sources can be a source of nutrient pollution. Nutrient pollution can cause excess algae growth in surface water, ultimately harming aquatic plants and animals. However, there is little evidence that runoff contamination occurs when liquid fish products are applied to crops correctly. The higher cost associated with liquid fish fertilizers when compared to manure or other compost sources may also discourage the overapplication that would lead to excess nutrient runoff.

Human health concerns

Liquid fish products are chemically stabilized with acid so most of the human health concerns relate to direct exposure and mild acid burns. The greatest potential for direct harm is if the product gets in a person's eyes; if it does, the effects are minimal unless exposure is prolonged. Prolonged or frequent skin contact can also cause allergic reactions. Correct application of liquid fish products minimizes any harmful contact, and the products do not leave an environmental residue that would be harmful to human health.

One possible concern that was not addressed in the 2006 TR is that fish materials can sometimes contain heavy metals and toxins that the fish accumulate during life. It is likely that the application of liquid fish products would introduce heavy metals into soils and crops; **regular testing of liquid fish products for heavy metals should be required, with maximum limits set and enforced.**

A long-term concern of the use of fish products in general is the chemical inputs to aquaculture systems. The public health implications of the use of antibiotics, antifungals, and other chemicals used in industrial fish production has not been fully explored.[68] As of yet there is no evidence to support a direct risk to human health from liquid fish products used in agricultural amendments, but the NOSB should be mindful of developments in aquaculture practices as it relates to the National List.

Another human health consideration that ties into environmental concerns is the abuse of workers. Liquid fish products are often derived from the byproduct of forage fish that are harvested for their oil and for pet and livestock feed. In some cases, the people who harvest

[67] NOAA Fisheries, Status of Stocks 2014: Annual Report to Congress on the Status of U.S. Fisheries. http://www.nmfs.noaa.gov/sfa/fisheries_eco/status_of_fisheries/archive/2014/2014_status_of_stocks_final_web.pdf

[68] Sapkota, A., A.R. Sapkota, M. Kucharski, J. Burke, S. McKenzie, P. Walker, P., et al. 2008. Aquaculture practices and potential human health risks: current knowledge and future priorities. Environment International 34:1215-1226. http://www.ncbi.nlm.nih.gov/pubmed/18565584

these fish may not be afforded basic human rights and will be forced to work as slaves.[69] This potential for harm, documented by the *New York Times*, includes human trafficking, physical abuse, starvation, and even death. **Tracking the origin of the fish product to ensure it is harvested in a manner that prevents human suffering is needed to preserve the integrity of organics.**

Crops Subcommittee action

The 2015 Crops Subcommittee's review concluded that while they found "no concerns with these substances that would prevent their renewal on the National List, [they] do want to emphasize the importance of the sustainable harvesting of fisheries." The subcommittee was also concerned that whole fish, rather than fish byproduct from other industries, would be used to make liquid fish products.

The subcommittee motion to remove liquid fish products from §205.601(j) as a plant and soil amendment was Yes: 0 No: 5 Abstain: 0 Absent: 0 Recuse: 0

CONCLUSION

The Cornucopia Institute **supports the relisting of liquid fish products** on the National List because of their current widespread and beneficial use, especially for plant starts. It is unclear whether natural alternatives exist that provide the same benefits of bio-availability, a fundamental nutrient profile, and ease of use.

In order to ensure that the use of liquid fish products remains in line with organic standards, it is necessary to minimize harm to the environment. It is essential that a comprehensive and current TR be produced before the next sunset review.

The NOSB should solicit input on the current source of fish material used in organic production to determine if sustainable sources are available and should set limits on the amount of heavy metals allowed to be present in the final product.

[69] 'Sea Slaves': The Human Misery That Feeds Pets and Livestock, by Ian Urbina, July 27, 2015. New York Times. Last accessed September 23, 2015. Available at: http://www.nytimes.com/2015/07/27/world/outlaw-ocean-thailand-fishing-sea-slaves-pets.html?_r=0

Soap-based Algicide/Demossers – 2017 Sunset

SUMMARY

The Cornucopia Institute **supports the Crops Subcommittee's vote to remove** soap-based algicide/demossers, scheduled to sunset in 2017, as synthetic substances allowed in organic crop production as algicides, disinfectants, and sanitizers, including irrigation system cleaning.[70] It is unclear how many organic producers are using soap-based control of algae and moss in their operations. **More investigation into the current uses of this material, if there are any, needs to be done before relisting is considered**.

In addition, soap-based algicides and demossers **may not be essential** for organic crop production as there are **natural and synthetic alternatives**. Investigation is needed to determine if there are situations when natural methods of controlling algae and moss fail, requiring direct intervention with soap-based products. The Cornucopia Institute recommends as a research priority a comparative study into the synthetic substances allowed for use as algicides, disinfectants, and sanitizers, to determine their relative compatibility with organic ideals. Specifically, if soap-based algicide and demossers are **safer**, more **environmentally friendly**, and **in use** by organic farmers when compared to other synthetic materials listed under §205.601(a), these substances should be considered for relisting.

If soap-based algicide/demossers are relisted, Cornucopia recommends including an **annotation stating that soap-based algicide/demossers can be used only when other physical, cultural, and mechanical means of control have proved insufficient and that the conditions for using the substance are documented in the Organic System Plan.**

Rationale:

- Soap-based algicides and demossers may be unnecessary for organic production because there are both allowed synthetic and natural alternatives to algae and moss control.
- Adopting conscientious management techniques to control algae and moss is consistent with organic farming and handling.[71]
- It is unclear how often soap-based algicide and demossers are utilized by organic farmers and whether they are essential to organic crop production.
- If natural methods of control fail, soap-based control of algae and moss may be a safer alternative than other synthetic materials allowed for use in organics.

DISCUSSION

Soap-based algicide and demossers are broadly composed of ammonium, potassium, and sodium salts of fatty acids. These "soap salts" are currently allowed in organic crop

[70] 7 CFR § 205.601(a)(7)
[71] 7 U.S.C. 6517(c)(1) National List – Guidelines for prohibitions or exemptions

production as algicides, disinfectants, and sanitizers, including irrigation system cleaning.

Algae and moss become problematic to organic farmers when they grow out of control. Both algae and moss proliferate in wet environments and can cause problems for walkways, greenhouse surfaces, and irrigation systems. Serious problems arise in irrigation systems, including irrigation ponds, by clogging pipes and polluting the water with excess organic matter.

Good management practices can generally prevent problems caused by the proliferation of algae and mosses before they get out of control. Whenever possible, changes in farm-management procedures should be the preferred method of controlling algae and moss overgrowth as holistic management practices are an ideal of organic farming.

Technical Report

There are <u>inconsistencies in the 2015 Technical Report</u> that need to be addressed before soap-based algicide and demossers are relisted under § 205.601. Though the Technical Report states that soap-based algicides and demossers allowed in organic production only contain potassium and ammonium salts of fatty acids, there is no basis for this in the regulations. In fact, sodium salts of fatty acids are commonly used as a basis for soap-based products. Sodium salts may **have a greater impact on human and environmental health that was not reviewed or discussed** by the Technical Report. If soap products using sodium salts are prohibited in organic crop production then that must be made clear in the regulations.

The 2015 Technical Report needs to be updated based on a new EPA report. The EPA released a revised report on soap salts in March 2015 that addresses the ecological impact of soap salts.[72] A new Technical Report should be prepared to take into account new data.

The Cornucopia Institute recommends the preparation of a new Technical Report to compare farmers' current methods of controlling algae and moss with allowed synthetic materials for their overall compatibility with organic guidelines.[73] The 2015 Technical Report lists the other synthetic compounds allowed for use as algicides, disinfectants, and sanitizers. This list includes alcohols, chlorine materials, copper sulfate (limited for use in aquatic rice systems), hydrogen peroxide, ozone gas, peracetic acid, and sodium carbonate peroxyhydrate. [74] What the TR does not discuss is whether these alternative synthetic substances are superior to soap salts with respect to their appropriateness in organic farming. The Board should consider the comparative effect on human and environmental

[72] Revised Environmental Fate and Ecological Risk Assessment for the Registration Review of Soap Salts, 2015. Page 5. Environmental protection Agency. Posted: 03/26/2015. ID: EPA-HQ-OPP-2008-0519-003. *Available at:* http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2008-0519-0030

[73] 7 U.S.C. 6517(c)(1) National List – Guidelines for prohibitions or exemptions

[74] 7 CFR § 205.601(a)

health, the necessity to organic farming, the unavailability of wholly natural substitutes, and consistency with organic farming ideals.[75]

The TR illustrates there are multiple natural alternatives for algae and moss control, possibly negating any need for soap-based synthetic products. **The Technical Report provides a good general discussion of natural alternative methods of control of algae and moss**. For example, physical control of the problem, such as power-washing, using filters, or providing proper drainage, is listed as a natural alternative. A new Technical Report should discuss and review any existing situations where natural methods of controlling moss and algae fail despite best efforts, requiring the use of synthetic compounds.

The Pesticide Research Institute for the USDA National Organic Program compiled the 2015 Technical Report. **The identities of the specific scientists who authored this report were withheld from the public**. It is vital that the public have access to information including the scientists' credentials and any institutional affiliations. Technical Reports must contain reliable information and should therefore come from a source without conflicts of interest or the suspicion of inherent bias.

The effects of soap-based compounds on human health

Soap-based compounds are considered inert and pose little risk to human health, even with direct exposure.[76] Soap salts break down quickly in the environment preventing any harmful effects from long-term exposure.[77]

There are some human health implications associated with direct contact to soap salt compounds.[78] Soap-based compounds can be severe eye irritants and can even be irritating to the skin in high concentrations. Ingestion of high doses of soap salts can cause indigestion and vomiting.[79] The actual risk of acute toxicity is very low even with cumulative exposure (including through ingestion and contact exposure).[80]

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[75] 7 U.S.C. 6517(c)(1) National List – Guidelines for prohibitions or exemptions

[76] 73 FR 39264. Ammonium Soap Salts of Higher Fatty Acids – Section III. Toxicological Profile. A Rule by **the** Environmental Protection Agency on 07/09/2008. *Available at:* https://www.federalregister.gov/articles/2008/07/09/E8-15516/ammonium-soap-salts-of-higher-fatty-acids-c8-

[77] Re-registration Eligibility Decision Document (RED): Soap Salts. 1992. U. S. Environmental ProtectionAgency, Office of Prevention, Pesticides and Toxic Substances. Available through the National Service Center for Environmental Publications*:* http://www2.epa.gov/nscep

[78] Potassium Salts of Fatty Acids – Fact Sheet (2001). Oregon State University. National Pesticide Information Center. *Available at:* http://npic.orst.edu/factsheets/psfagen.pdf

[79] Weinzierl, R.; Henn, T. *Alternatives in Insect Pest Management: Biological and Biorational Approaches.* North Central Regional Extensions Publication (1991). Accessed October, 2015, Vista/University of Illinois Abstract. http://www.ag.uiuc.edu/~vista/abstracts/aaltinsec.html

[80] 73 FR 39264. Ammonium Soap Salts of Higher Fatty Acids – Section IV. Aggregate Exposures. A Rule by the Environmental Protection Agency on 07/09/2008. *Available at:* https://www.federalregister.gov/articles/2008/07/09/E8-15516/ammonium-soap-salts-of-higher-fatty-acids-c8-

Alternatives exist

There are alternative methods for controlling algae and moss in organic crop production. As already discussed, the 2015 Technical Report provides a list of synthetic substances and products that are currently allowed for the same use as soap-based algicides and demossers.

Algae and moss control can often be achieved through good farm management practices. For algae, the Purdue Extension notes that maintaining proper ventilation, avoiding over-watering, reducing or draining areas where water collects, and maintaining appropriate fertilizer levels will help control algae growth.[81] Excessive fertilizer use prompts algae blooms in irrigation systems and ponds, as algae flourish in the presence of excess nitrogen and phosphorus.[82] The organic breakdown of barley straw has also been studied as an effective control of algae in ponds and irrigation systems.[83]

Physical management is a natural alternative that should be encouraged in organic farming. Both moss and algae are affected by the type of growing surface, preferring wood or other organic matter in a moist environment. Therefore, regular weeding and cleaning of organic detritus helps prevent moss and algae growth. Power-washing and other forms of direct removal are also effective moss management techniques.

Environmental concerns

There are some known environmental risks associated with the use of soap salts. The U.S. Environmental Protection Agency (EPA) has assessed the ecological risk of the ammonium, potassium, and sodium salts of fatty acids that compose soap-based algicide and demossers.[84]

Plants that are exposed to "spray drift" may experience toxic effects of soap salts. Often it is plants with "hairy" foliage that traps the soap salts and causes contact burns. Otherwise soap salts do not persist long enough on foliage to cause damage. They are often used to control soft-bodied insects, including aphids, without harm to the plants.

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[81] Controlling Algae in Irrigation Ponds - Purdue Extension. By Diane M. Camberato and Roberto G. Lopez, Purdue Horticulture and Landscape Architecture. *Available at:* https://www.extension.purdue.edu/extmedia/ho/ho-247-w.pdf

[82] Chapter 3: Fertilizers as water pollutants. Food and Agriculture Organization of the United Nations. Produced by: Natural Resources Management and Environment Department. *Available at:* http://www.fao.org/docrep/w2598e/w2598e06.htm

[83] Information Sheet 1: Control of Algae with Barley Straw. Centre for Aquatic Plant Management, Centre for Ecology and Hydrology (UK). *Available at:* http://www.researchgate.net/publication/233867874_Centre_for_Aquatic_Plant_Management_INFORMATION_SHEET_1_CONTROL_OF_ALGAE_WITH_BARLEY_STRAW

[84] Revised Environmental Fate and Ecological Risk Assessment for the Registration Review of Soap Salts, 2015. Page 5. Environmental Protection Agency. Posted: 03/26/2015. ID: EPA-HQ-OPP-2008-0519-003. *Available at:* http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2008-0519-0030

Soap salts were found to **cause mortality in honey bees, up to 30%**, when they were directly exposed, to the degree that their bodies were sprayed or painted. The EPA notes that these mortality rates should transfer to other **terrestrial invertebrates** and that spray drift does have an effect on invertebrate health depending on actual exposure levels. This is a concern because the presence and vitality of **beneficial insects**, including bees, are essential to organic agriculture. Soft-bodied invertebrates may be more sensitive to soap-based compounds. **Beneficial soil organisms** (including earthworms and nematodes) can be harmed when exposed to soap salts.

Aquatic organisms are more sensitive to soap salts than their terrestrial counterparts. The EPA determined that freshwater invertebrates and crustaceans were very sensitive to types of soap salts, while fish and other organisms have lesser degrees of sensitivity.[85] As expected, soap compounds have a detrimental effect on algae and non-vascular plant growth. While this toxic effect is useful for use as an algicide and demosser, if soap-based compounds are washed or released into surface waters they can have a cascading effect on those ecosystems.

It is uncertain how often soap-based compounds enter the environment or what their current impacts might be. Real-world environmental impacts are subtle and poorly studied. Because soap-based compounds break down quickly in the environment, harmful contact may be brief. Ecosystems most at risk will be downwind and downstream of the area of application.

Crops Subcommittee action

The subcommittee proposed to remove soap-based algicide/demossers from §205.601(a)(7) based on concerns that the use of this material did not meet the OFPA criteria for "Compatibility and Alternatives."[86] They did not receive any comments regarding why soap-based algicide/demossers are necessary for organic production.

The vote in the subcommittee to remove soap-based algicide/demossers from §205.601(a)(7) was: Yes: 5 No: 0 Abstain: 0 Absent: 1 Recuse: 0

CONCLUSION

The Cornucopia Institute **supports the Crops Subcommittee's vote to remove** soap-based algicide/demossers as a synthetic substance used in organic crop production due to lack of essentiality. Natural alternative methods of control of algae and moss include power-washing, the use of filters, or providing proper drainage.

[85] Revised Environmental Fate and Ecological Risk Assessment for the Registration Review of Soap Salts (2015). Page 6. Environmental Protection Agency. Posted: 03/26/2015. ID: EPA-HQ-OPP-2008-0519-003. *Available at:* http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2008-0519-0030

[86] Organic Foods Production Act (OFPA), 7 CFR 205.600(b)

Soaps, insecticidal – 2017 Sunset

SUMMARY

The Cornucopia Institute **supports the relisting of insecticidal soaps** as scheduled to sunset in 2017, as synthetic substances allowed in organic crop production as insecticides (including acaricides or mite control).[87] Insecticidal soaps are essential for organic crop production because they offer a safe synthetic control of certain pest insects when natural management techniques fail.

The Cornucopia Institute **recommends the preparation of a Technical Review** to verify that insecticidal soaps are compatible with organic agriculture. **The 1994 Technical Advisory Panel (TAP) review is woefully incomplete and out of date.** In addition, we recommend prioritizing research into the synthetic substances allowed for use as insecticides, to determine their relative compatibility with organic ideals. Specifically, if soap insecticides are **safer**, more **environmentally friendly**, and **in use** by organic farmers when compared to other synthetic materials listed for use as insecticides under §205.601(a), these substances should be relisted.

Rationale:

- Adopting conscientious management techniques to control insect pest are consistent with organic farming and handling, but when those techniques fail organic farmers need access to safe alternative methods of pest control.[88]
- Insecticidal soaps are an effective control of soft-bodied pest insects.
- Insecticidal soaps may be a safer alternative with respect to human and environmental health than other synthetic materials allowed for use as insecticides.
- There may be impacts on beneficial insects and other environmental factors that need to be explored in a Technical Review.

DISCUSSION

"Soap" is a general term for the salts of fatty acids. Soap-based synthetic materials can be broadly composed of ammonium, potassium, and sodium salts of fatty acids. These "soap salts" are currently allowed in organic crop production as insecticides. Potassium soap salts are most used in insect control because they seem to have the greatest impact on the types of pests they are used to control.[89]

Soaps are a good method of controlling infestations of soft-bodied insects (including aphids, scales, thrips, and mealybugs) in organic crops. The fatty acids in soaps target and

[87] 7 CFR §205.601(e)(8) - As insecticides (including acaricides or mite control).

[88] According to §205.601, synthetic substances allowed for use in organic crop production may only be used when the provisions set forth in §205.206 (a) – (d).

[89] Revised Environmental Fate and Ecological Risk Assessment for the Registration Review of Soap Salts, 2015. Page 3. Environmental protection Agency. Posted: 03/26/2015. ID: EPA-HQ-OPP-2008-0519-003. *Available at:* http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2008-0519-0030

degrade the pest's exoskeleton, causing the insect to dehydrate and die. These compounds are considered "contact insecticides": they are effective only when insect or mite pests come into direct contact with the wet spray. Soap residues degrade rapidly under normal conditions, so a pest insect's exposure to dried residue will have little effect.[90] However, the fact that soap degrades quickly has some benefits: it poses a low risk to human health and environmental contamination.

A new Technical Review was not created for insecticidal soaps, perhaps because the soaps used as algicides and demossers have the same active ingredients as algicides and demossers soaps and a Technical Report was prepared in early 2015 for those. However, the commercial formulation of insecticidal soaps and soap-based algicide and demossers are often very different and even includes different types of "soap salts."

Technical Report

There is no current Technical Review for insecticidal soaps and the 1994 TAP is <u>woefully out of date</u>. It was reviewed by Dr. Heimut Ried, James Johnson, Philip Van Buskick, Paul Sachs, Joseph Kovack, Sam Cotner, and Donald Blakeney. The 1994 TAP review utilizes data from the Environmental Protection Agency's (EPA) <u>1992</u> RED report – another completely out of date document. In the overall conclusion of the TAP report, in the OFPA criteria section, under 2119(m)(5): "biology", it states: "Impact on beneficial insects needs more research."

A related Technical Review for soap-based algicide and demossers was produced in early 2015 (authors undisclosed by the NOP). Soap-based algicide and demossers and insecticidal soaps do contain some of the same active ingredients. However, commercial formulations are not the same. In addition, the uses of these synthetic products are quite different, necessitating the preparation of a Technical Review specifically for insecticidal soaps.

A new Technical Review should be complied before the next sunset date to determine what kinds of soaps are currently in use in organic agriculture and what their specific effects on human health and the environment (including beneficial insects) may be. The Regulations are also unclear on what types of soaps are allowed for use as insecticides. The Crops Subcommittee notes that "soaps consist of salts of fatty acid anions and potassium, sodium, or ammonium cations" without acknowledging that the related 2015 Technical Review for soap-based algicide and demossers only speaks to potassium and ammonium soap salts. While insecticidal soaps are generally composed of potassium fatty acid salts, there is no basis for this in the regulations. **Sodium salts may have a greater impact on human and environmental health that was not reviewed or discussed by the related 2015 Technical Review** at all. If soap products using sodium and ammonium soap salts are prohibited for use as insecticides, then that must be made clear in the regulations.

[90] *Understanding Insecticidal Soaps and Detergents*, May 27th, 2009 by Raymond A. Cloyd. Last accessed Oct 7, 2015, at: https://greenmethods.com/understanding-insecticidal-soaps-and-detergents/

A new Technical Review should also discuss whether there are natural alternatives to the use of insecticidal soaps. Given there are natural methods of controlling pests, including trap crops, attracting beneficial insects, physical barriers, intercropping, and variety selection, **The Cornucopia Institute recommends including an annotation stating that Insecticidal Soaps can only be used when other physical, cultural, and mechanical means of control have proved insufficient** and that the conditions for using the substance are documented in the organic system plan.

The EPA released a revised report on soap salts in March, 2015 that addresses the ecological impact of soap salts.[91] The 2015 Technical Review for soap-based algicide and demossers did not include this updated data.

Finally, it is vital that the public have access to information including the scientists' credentials and any institutional affiliations. Technical Reviews must contain reliable information and should therefore come from qualified sources without conflicts of interest or suspicions of inherent bias.

The effects of insecticidal soaps on human health

Soap-based compounds are considered inert and pose little risk to human health, even with direct exposure.[92] Soap salts break down quickly in the environment preventing any harmful effects from long-term exposure.[93]

There are some human health implications associated with direct contact to soap salt compounds.[94] Soap-based compounds can be severe eye irritants and can even be irritating to the skin in high concentrations. Ingestion of high doses of soap salts can cause indigestion and vomiting.[95] The actual risk of acute toxicity is very low even with cumulative exposure (including through ingestion and contact exposure).[96]

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[91] Revised Environmental Fate and Ecological Risk Assessment for the Registration Review of Soap Salts, 2015. Page 5. Environmental protection Agency. Posted: 03/26/2015. ID: EPA-HQ-OPP-2008-0519-003. *Available at:* http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2008-0519-0030

[92] 73 FR 39264. Ammonium Soap Salts of Higher Fatty Acids – Section III. Toxicological Profile. A Rule by the Environmental Protection Agency on **07/09/2008**. *Available at:* https://www.federalregister.gov/articles/2008/07/09/E8-15516/ammonium-soap-salts-of-higher-fatty-acids-c8-

[93] Re-registration Eligibility Decision Document (RED): Soap Salts. 1992. U. S. Environmental Protection Agency, Office of Prevention, Pesticides and Toxic Substances. Available through the National Service Center for Environmental Publications*:* http://www2.epa.gov/nscep

[94] Potassium Salts of Fatty Acids – Fact Sheet (2001). Oregon State University. National Pesticide Information Center. *Available at:* http://npic.orst.edu/factsheets/psfagen.pdf

[95] Weinzierl, R.; Henn, T. *Alternatives in Insect Pest Management: Biological and Biorational Approaches.* North Central Regional Extensions Publication (1991). Accessed October, 2015, Vista/University of Illinois Abstract. http://www.ag.uiuc.edu/~vista/abstracts/aaltinsec.html

[96] 73 FR 39264. Ammonium Soap Salts of Higher Fatty Acids – Section IV. Aggregate Exposures. A Rule by the Environmental Protection Agency on 07/09/2008. *Available at:* https://www.federalregister.gov/articles/2008/07/09/E8-15516/ammonium-soap-salts-of-higher-fatty-acids-c8-

Environmental concerns

There are some known environmental risks associated with the use of soap salts. The US Environmental Protection Agency (EPA) has assessed the ecological risk of the potassium salts of fatty acids that compose most soap-based insecticides.[97]

Plants and animals that are exposed to "spray drift" may experience toxic effects of soap salts. It is possible that plants with "hairy" foliage may trap the soap salts and cause contact burns. Insecticidal Soaps can control soft-bodied insects without any harm to the plants or crop production.

Studies found that toxicity was negligible for birds and mammals.[98] Aquatic organisms are more sensitive to soap salts than their terrestrial organisms. The EPA determined that freshwater invertebrates and crustaceans were very sensitive to types of soap salts, while fish and other organisms have lesser degrees of sensitivity.[99]

Soap salts were found to cause mortality in honey bees, up to 30%, when they were directly exposed (to the degree that their bodies were sprayed or painted). The EPA notes that these mortality rates should transfer to other terrestrial invertebrates and that spray drift does have an effect on invertebrate health depending on actual exposure levels. This is a concern because the presence and vitality of beneficial insects, including bees, are essential to organic agriculture.

Soft-bodied invertebrates are very sensitive to soap-based compounds; this is why they are effective insecticides. However, some soft-bodied insects are beneficial (such as predatory mites) and will be negatively affected by their use. This potential harm on beneficial insect populations can be minimized by judicious uses, such as spot applications on infested plants or field sections. Beneficial soil organisms (including earthworms and nematodes) can also be harmed when directly exposed to soap insecticides but the EPA notes that normal application practices should make this risk negligible.

Careful management can allow for the use of insecticidal soaps without hurting beneficial insects. The Oregon State University's IPM program[100] suggests a strategic approach: using a soap-based knock-down spray prior to releasing beneficial predator insects. This is

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[97] Revised Environmental Fate and Ecological Risk Assessment for the Registration Review of Soap Salts, 2015. Page 5. Environmental Protection Agency. Posted: 03/26/2015. ID: EPA-HQ-OPP-2008-0519-003. *Available at:* http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2008-0519-0030

[98] Revised Environmental Fate and Ecological Risk Assessment for the Registration Review of Soap Salts, 2015. Page 5. Environmental Protection Agency. Posted: 03/26/2015. ID: EPA-HQ-OPP-2008-0519-003. *Available at:* http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2008-0519-0030

[99] Revised Environmental Fate and Ecological Risk Assessment for the Registration Review of Soap Salts (2015). Page 6. Environmental Protection Agency. Posted: 03/26/2015. ID: EPA-HQ-OPP-2008-0519-003. *Available at:* http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2008-0519-0030

[100] OSU Oregon State University – Pacific Northwest Nursery IPM – Mites. *Available at:* http://oregonstate.edu/dept/nurspest/two-spottedmite.htm

corroborated on the Planet Natural website[101] which states, "On heavier infestations, it is important that you first reduce the pest infestation before releasing beneficial insects. Consider spraying with an insecticidal soap or other natural insect control."

Essentiality; alternatives exist

Natural alternatives for the control of soft-bodied insect pests start with farm management techniques. According to §205.601, synthetic substances allowed for use in organic crop production may only be used when the provisions set forth in §205.206 (a) – (d) **prove insufficient to prevent or control the target pest.** These provisions suggest various management practices and approaches to prevent or control crop pests, including:

- Crop rotations, crop nutrient, and soil management practices; sanitation measures to remove habitat for pest organisms; cultural practices that enhance crop health;
- Mechanical or physical methods, such as removing pests by hand;
- Natural predator conservation and augmentation by way of development of habitat for natural predators or introduction of predators or parasites of the pest species; non-synthetic controls such as lures, traps, and repellents.

These natural management techniques are the best way to control soft-bodied insects because they promote organic ideals. For example, healthy soil implies healthy plants that are naturally more resistant to pests. Cultural practices can enhance crop health through the selection of plant species and varieties adapted to local conditions and inborn resistance to prevalent pests. Developing habitat for natural predators, like wasps, can be achieved by maintaining a wildflower buffer strip around fields.

As a last resort, allowed synthetic substances can be used. There are several synthetic insecticides that can be employed instead of insecticidal soaps at this time:[102]

- Ammonium carbonate
- Aqueous potassium silicate
- Boric acid
- Copper sulfate
- Elemental sulfur
- Lime sulfur
- Horticultural oils
- Sticky traps/barriers
- Sucrose octanoate esters

These alternative substances do not necessarily replace insecticidal soaps. In fact, because insecticidal soaps have low toxicity to humans and the environment, if a synthetic substance must be used, insecticidal soaps may be more compatible with organic agriculture than other methods of pest control. Insecticidal Soaps are essential to many

[101] http://www.planetnatural.com/beneficial-insects-101/phytoseiulus-persimilis/
[102] 7 CFR §205.601(e)

organic farmers because they effectively control soft-bodied pests and are safe for use by their human handlers.

NOSB Crops Subcommittee action

The Crops Subcommittee received supporting commentary for the relisting of insecticidal soaps. Specifically, the comments noted that "…some organic producers use Insecticidal Soaps regularly, and they rated Insecticidal Soaps as critical to the success of their operations."

Overall, the Subcommittee had had no concerns regarding the relisting of insecticidal soaps under 7 CFR §205.601(e) as insecticides. The vote in the subcommittee to remove insecticidal soaps from §205.601(e) (8) was as follows:
Yes: 0 No: 5 Abstain: 0 Absent: 0 Recuse: 0

CONCLUSION

The Cornucopia Institute **supports the relisting** of insecticidal soaps as a synthetic substance used in organic crop production. Insecticidal soaps are used by many farmers in organic agriculture to control soft-bodied pest insects when natural management techniques fail. Soap salts in general are relatively safe for humans and the risks to the environment are low.

The Cornucopia Institute also recommends that a Technical Report for insecticidal soaps be prepared before the next sunset review. It is essential to review and discuss the uses of soaps as insecticides and **their impact on beneficial insects**.

It also may be necessary to annotate or alter the regulations to reflect whether potassium, ammonium, or sodium salts of fatty acids are allowed in insecticidal soaps approved for organic use. While insecticidal soaps are generally composed of potassium soap salts, there is no basis for this in the regulations.

Vitamin D_3 – 2017 Sunset

SUMMARY

The Cornucopia Institute **opposes the relisting** of vitamin D_3 as a rodenticide under §205.601(g), synthetic substances allowed for use in organic crop production without the addition of an annotation restricting its use to only after more ecologically sound alternatives have been tried first. Though vitamin D_3 is considered one of the safest rodenticides, it is known to harm non-target animals.

Rationale:

- Vitamin D_3 has a low risk of poisoning humans when used properly.
- Compared to several other rodenticides, vitamin D_3 has a lower overall risk to birds and mammals, but there is evidence that **it can bio-accumulate**.
- Details of the chemical synthesis of cholecalciferol (vitamin D_3) involve up to 18 steps and are subject to several patents that are not publicly available.
- The 2011 Technical Review compiled by ICF International states that effective alternatives exist, including trapping, that are in line with OFPA.

DISCUSSION

Vitamin D_3 is naturally produced in the body through a multi-step pathway involving the skin, liver, and kidneys. It functions to increase the calcium uptake in bones and to move calcium from the intestine to the blood.[103] Cholecalciferol, a synthetic derivative of vitamin D_3, is the form used as the active ingredient in rodenticides for gophers, mice, and rats. Cholecalciferol is considered synthetic due to the extraction process that uses solvents and ultraviolet light. When ingested by rodents, vitamin D_3 results in elevated levels of calcium in the blood leading to calcification of major organs.[104, 105] Tissue damage results in circulatory problems, kidney failure, and eventually death.[106]

Vitamin D_3 was approved for use as a rodenticide in 1984 by the U.S. EPA.[107] In 2008, a risk mitigation decision by the EPA required vitamin D_3 to be sold to general and residential

[103] Holick, M. 1999. "Evolution, Biologic Functions, and Recommended Dietary Allowances of Vitamin D." in Holick, M. (ed.), 1999. Vitamin D: Physiology, Molecular Biology, and Clinical Applications. Humana Press, Inc., Totowa, NJ., pp. 1-16.

[104] ATTRA, 2010b, National Sustainable Agriculture Information Service. Retrieved November 20, 2010 from http://attra.ncat.org/calendar/question.php/2006/03/20/what_rodenticides_are_acceptable_for_use

[105] Marshall, E., 1984. Cholecalciferol: A Unique Toxicant for Rodent Control. Proceedings Eleventh Vertebrate Pest Conference. Retrieved November 18, 2010 from http://digitalcommons.unl.edu/cgi/viewcontent.cgi?article=1021&context=vpc11

[106] 2011 Technical Report http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5089352&acct=nopgeninfo

[107] U.S. EPA. 2010. Registration Review: Conventional Cases Schedule: 2010-2013. U.S. Environmental Protection Agency, June 7, 2010. Retrieved November 17, 2010 from http://www.epa.gov/oppsrrd1/registration_review/2010-13-conventional.pdf

consumers only with bait stations. Loose bait (pellets and meal, for example) were prohibited. This measure was enacted to reduce children's exposure to rodenticides.[108]

One of the key concerns about rodenticides, in general, is the effect on non-target species. Non-target species can be poisoned either by eating the bait directly (primary risk) or by predators or scavengers feeding on an animal that has ingested bait (secondary risk).[109]

Environmental concerns

Because they are designed to kill small mammals and are not species specific, all rodenticides pose a high potential primary risk to non-target species. In an EPA comparative study of nine rodenticides, vitamin D_3 was deemed to have a low to moderate primary risk to birds and a high primary risk for mammals. Insufficient data was available to assess secondary risk. However, one study showed that vitamin D_3 has a long retention time in the blood (25 days), which could lead to a higher risk to predators or scavengers compared to poisons that are eliminated quickly. Vitamin D_3's retention time in the liver of poisoned animals is unknown.[110]

Another concern with all rodenticides is their potential sublethal effect on birds and mammals. These effects are unknown and reproduction studies are needed to establish a no-observable-adverse-effects level (NOAEL, toxicity threshold).[111]

A New Zealand study noted that there are species differences with respect to susceptibility to vitamin D_3 and that variations among individuals even within a species occurs. Different bird species exhibit considerable variations in their sensitivity to vitamin D_3; bait put in the field should be placed with care to minimize bird exposure. While cats in this study did not show any adverse reaction to vitamin D_3, dogs and horses exhibited adverse effects including increased calcium and urea nitrogen in the blood and possible renal damage. Vitamin D_3 has a lower secondary risk of poisoning pets than other vertebrate rodenticides, but utilization of vitamin D_3 by pet owners, especially dog owners, should be discouraged.[112]

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[108] U.S. EPA, 2008. Risk Mitigation Decisions for Ten Rodenticides. Retrieved November 19, 2010 from http://www.epa.gov/pesticides/reregistration/rodenticides/

[109] U.S. EPA. 2004. Potential Risks of Nine Rodenticides to Birds and Nontarget Mammals: a Comparative Approach. Retrieved March 21, 2015 from http://pesticideresearch.com/site/docs/bulletins/EPAComparisonRodenticideRisks.pdf

[110] Ibid.

[111] U.S. EPA. 2004. Potential Risks of Nine Rodenticides to Birds and Nontarget Mammals: a Comparative Approach. Retrieved March 21, 2015 from http://pesticideresearch.com/site/docs/bulletins/EPAComparisonRodenticideRisks.pdf

[112] Eason, C.T, Wickstrom, M., Henderson, R., Milne,L and Arthur, D. Non-target and Secondary Poisoning Risks Associated With Cholecalciferol. New Zealand Plant Protection 53:299-304, 2000. Retrieved March 27, 2015. http://www.nzpps.org/journal/53/nzpp_532990.pdf

Essentiality

Rodent control is considered essential to crop production because major crop losses can result from rodent infestations. Rodent damage from chewing irrigation lines leads to waste of irrigation water and crop loss. Also, crop losses occur when flood irrigation water goes down rodent burrows instead of irrigation furrows. While many rodenticides exist, they are not approved for use on organic farms and are much more toxic to birds and mammals than vitamin D_3.

Alternatives exist

There are many acceptable methods of rodent control on organic farms that do not involve chemicals. From the TR: "A majority of organic farmers rely on trapping for some level of rodent control." Additional methods include encouraging predators such as corn and rat snakes, cats, and owls (for example, putting up owl nest boxes or encouraging wetlands to attract raptor nesting); making areas less hospitable to rodents (for example, removing shelter or food sources); and using physical barriers (for example, fences, trenches, irrigation).[113] Castor bean oil spray or pellets can also be used in organic production, although castor oil can also be poisonous to pets.[114] Other deterrents include rotten eggs, animal scents, hair, daffodils, red squill, and euphorbia. Sonic alarms and urea are also alternatives, but their effectiveness has not been studied.

Sulfur dioxide was previously on the National List for rodent control, but was removed at its 2012 sunset with a vote of No: 5 and Yes: 9 (a two-thirds majority was required to relist at the time).

Human health concerns

Vitamin D_3 can be toxic to humans at doses greater than 0.5 mg/kg.[115] Dogs have an oral LD_{50} of 88 mg/kg. If this were extrapolated to humans, a 110-pound person would have to consume an equivalent of 440,000 of the 400 unit vitamin D_3 capsules to have the same effect. Thus, the risk to humans of vitamin D_3 toxicity through poisoning is low.[116] Data from the Annual Poison Center Report showed that in 2004 there were six human exposures in the U.S. to vitamin D_3 rodenticide, and in 2010 there were 13, two of which required hospitalization.[117]

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[113] https://attra.ncat.org/calendar/question.php/how_can_i_control_rodents_organically
[114] 2011 Technical Report
http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5089352&acct=nopgeninfo
[115] 2011 Technical Report
http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5089352&acct=nopgeninfo
[116] Ibid.
[117] Quarrels, W., Protecting Raptors from Rodenticides. Common Sense Pest Control Quarterly, Vol.XXVII, No. 1-4, Special Issue 2011 (Published January 2013). http://www.birc.org/RaptorQ.pdf

The most vulnerable population for poisoning is children, who are particularly susceptible to toxins in the environment because of their small size and behavior. EPA's 2008 requirement to sell vitamin D_3 to the general public only with bait stations is meant to minimize vitamin D_3 poisoning in children.[118]

Eating game from poisoned animals may also pose a threat. Human health hazards would be increased if hunted animals were primary consumers of the bait.[119] A New Zealand study demonstrated adverse reactions in dogs who ate poisoned possum meat and recommended that hunters not take game from areas baited with vitamin D_3 in the last one to three months.[120]

Past NOSB deliberations

The Crops Subcommittee discussed the lack of effectiveness of traps and other methods and the fact that public comments during the Spring 2015 NOSB meeting were divided. Public commentary concerned the potential for toxicity to non-target animals as well as to children and pets. The subcommittee requested input from the public as to whether non-synthetic rodenticides are effective and should be considered as viable alternatives.

The Crops Subcommittee motion to remove vitamin D_3 from §205.601(g) on the National List was Yes: 0 No: 6 Abstain: 0 Absent: 0 Recuse: 0.

CONCLUSION

The Cornucopia Institute **opposes** the relisting of vitamin D_3 on the National List under §205.601(g) synthetic substances allowed for use in organic crop production without an annotation requiring documentation to the certifier that less toxic alternatives, outlined above, have failed. Vitamin D_3 is toxic to non-target organisms. Trapping is a safer, effective alternative that meets OFPA criteria.

[118] U.S. EPA, 2008. Risk Mitigation Decisions for Ten Rodenticides. Retrieved November 19, 2010 from http://www.epa.gov/pesticides/reregistration/rodenticides/

[119] https://attra.ncat.org/calendar/question.php/how_can_i_control_rodents_organically

[120] Eason, C.T, Wickstrom, M., Henderson, R., Milne,L and Arthur, D. Non-target and Secondary Poisoning Risks Associated With Cholecalciferol. New Zealand Plant Protection 53:299-304, 2000. Retrieved March 27, 2015. http://www.nzpps.org/journal/53/nzpp_532990.pdf

PROPOSED ANNOTATION CHANGE

Micronutrients

SUMMARY

The Crops Subcommittee proposes to change the listing of micronutrients on §205.601 as follows:

> §205.601 (j) As a plant or soil amendment.
> (6) Micronutrients—not to be used as a defoliant, herbicide, or desiccant. Those made from nitrates or chlorides are not allowed. ~~Soil d~~**Deficiency** must be documented ~~by testing~~.
> (i) Soluble boron products.
> (ii) Sulfates, carbonates, oxides, or silicates of zinc, copper, iron, manganese, molybdenum, selenium, and cobalt.

The Cornucopia Institute **opposes the annotation change to micronutrients** proposed by the Crops Subcommittee because it **encourages the use of synthetic micronutrients without adequate documentation to demonstrate need**. Rather, we support an annotation that allows **verifiable site-specific documentation** and requires the producer to document a site-specific process for increasing soil nutrients into the Organic System Plan (OSP). Therefore, we would support the following annotation change: "Soil deficiency must be demonstrated by verifiable site-specific documentation that is accompanied by an OSP to *organically* build and maintain soil micronutrients."

Rationale:

- The proposed annotation change allows for micronutrient deficiencies to be documented by other types of testing (e.g., tissue), professional recommendation, or published information specific to a crop or region.
- Confirmation of known regional deficiencies "by cooperative extension agents and publications" is problematic because such opinions and publications are not necessarily based on evidence at the site, and some of these experts continue to hold biases against organic production.
- Reliance on synthetic micronutrients is counterproductive to building healthy soils and not in line with OFPA. Growers should instead develop a fertility plan that includes livestock as part of the farming system, cover crops, mulches, composts, and other inputs to build and maintain micronutrient supplies in the soil.
- Growers who depend on regular inputs of micronutrients need to modify fertility practices in their OSP.
- We support an annotation that allows for a variety of site-specific documentation options and requires growers to integrate into the OSP a management process that fosters soil health and fertility through the judicious use of soil-building practices.

DISCUSSION

Micronutrients are widely used by organic farmers to correct deficiencies in areas with regionally deficient soils or crops with particular micronutrient needs. Concerns over the existing annotation are based on the fact that it requires documentation of **soil** testing showing a deficiency before micronutrients can be applied, rather than "a proactive action to keep an organic agroecosystem in balance."[121] The Crops Subcommittee, therefore, has stated that the limitation to document a micronutrient deficiency to only soil testing is "outdated and needs a more comprehensive approach."

Public comments for the Spring 2015 meeting listed other viable ways to determine micronutrients deficiencies, including:

- Plant sap testing;
- Tissue testing;
- Known regional deficiencies, such as zinc, iron, and boron, that are confirmed by cooperative extension agents and publications; and
- Professional crop advisors and agronomists who know the nutrient needs of specific crops and regions and can write recommendations for correction before the problem of deficiency occurs.

Public comment also noted that there may be soil characteristics that inhibit the uptake of a particular micronutrient into the plant—such as pH, cation-exchange capacity (CEC), and electrical conductivity (EC)—even though a soil test shows that the micronutrient is present in adequate amounts in the soil. In these cases a professional agronomist or crop advisor could determine that a nutrient was deficient, even if a soil test indicated otherwise. Farmers from Western arid states also commented that they have had little improvement in the micronutrient concentration in soils at the levels needed for certain crops despite efforts to build soil over a number of years.

The Cornucopia Institute noted that some of these comments came from larger, split conventional/organic operations that have a predisposition to practice "organics by substitution," rather than a more holistic approach to nutrient management.

General comments pertaining to annotation changes

Under the new sunset process, unilaterally changed by the NOP on September 16, 2013, without public hearing or comment, the NOP policy now explicitly prohibits annotations at sunset. The NOP has failed to follow the legally prescribed public process when changing the rules governing the NOSB's policies and procedures. Although we support the adoption of changes at sunset to annotations that limit, but do not expand, uses of synthetic materials, the NOP has disallowed this procedure.

[121] http://www.ams.usda.gov/sites/default/files/media/NOSB%20All%20Oct%202015%20Proposals.pdf

In spite of this, NOSB subcommittees are proposing to move forward listings with changed annotations along with a vote on sunset—for micronutrients and List 4 "inerts" on §205.601, List 4 "inerts" on §205.603, and flavors on §205.605(a). In addition, the Handling Subcommittee is proposing to change the listings of alginic acid from §205.605(a) to §205.605(b) and carnauba wax from §205.605(a) to §205.606. These actions are not allowed under the current NOP-directed sunset procedure.

This **abuse of agency discretion** and failure to comply with administrative procedure regarding reinterpretations of rules governing materials review undermines a historically transparent and collaborative process as well as the legal requirements in administering the NOP and the NOSB. If the NOP and NOSB believe that there are instances in which the Board should modify annotations and/or list at sunset then the NOP must revoke its policy and reinstate the Board's previously adopted policy concerning adopting changes to annotations at sunset.

Crops Subcommittee vote

The Crops Subcommittee proposed changes to the listing of micronutrients on §205.601 as follows:

> §205.601 (j) As a plant or soil amendment.
> (6) Micronutrients—not to be used as a defoliant, herbicide, or desiccant. Those made from nitrates or chlorides are not allowed. ~~Soil d~~**Deficiency** must be documented ~~by testing~~.
> (i) Soluble boron products.
> (ii) Sulfates, carbonates, oxides, or silicates of zinc, copper, iron, manganese, molybdenum, selenium, and cobalt.

The Crops Subcommittee vote for the annotation change was Yes: 5 No: 0 Abstain: 0 Absent: 0 Recuse: 0.

CONCLUSION

The Cornucopia Institute **opposes the annotation change** proposed by the Crops Subcommittee because it allows for the use of synthetic micronutrients without empirical evidence to demonstrate need. Rather, we suggest that the following annotation is more in line with OFPA: "**Soil deficiency must be demonstrated by verifiable site-specific documentation that is accompanied by an OSP designed to build and maintain soil micronutrients.**" We suggest that the current motion be sent back to the Crops Subcommittee for the development of an annotation that could be considered with the sunset proposal in spring 2016.

PETITIONED MATERIALS

Laminarin and Seaweed Extracts

SUMMARY

The Cornucopia Institute **opposes** the proposal by the Crops Subcommittee to classify **laminarin**, for use as a stimulant of plant defense responses, as non-synthetic because of the **synthetic extraction process**. The non-synthetic classification would therefore allow laminarin to be used in organic crop production without being required to be added to the National List.

Using the same rationale, we **support** the proposal of the Crops Subcommittee to **classify seaweed extracts as synthetic** and to deny the petition for listing on §205.601 for use as a fertilizer.

Rationale:

- The extraction of laminarin and seaweed extract uses synthetics, sulfuric acid and sodium hydroxide, that remain in the final product.
- The use of laminarin and seaweed extract activates plant secondary metabolites and plant defense chemicals that alter the chemical composition of the harvested crop.
- Seaweed extracts are a synthetic fertilizer and as such should not be added to the National List.

DISCUSSION

Laminarin is extracted from a brown seaweed, *Laminaria digitata*, for use in formulating the product Vacciplant (EPA Reg. No. 83941-2). It is sprayed onto plants to induce systemic acquired resistance (SAR), an innate immune defense response against plant diseases that elicits plant defense compounds.

In June 2013, the NOSB received a petition from the manufacturer, Laboratoires Goëmar SA, for laminarin for use in disease control. The Crops Subcommittee voted that it was non-synthetic by a vote of 5-2-0 and brought it to the full NOSB in the spring of 2014. The NOSB then decided that there needed to be **a Limited Scope Technical Review** (TR) to clarify whether the extraction and purification process resulted in a synthetic material, and to examine the environmental effects of seaweed harvest and processing. That TR was completed in May 2015 by OMRI.[122]

[122] http://www.ams.usda.gov/sites/default/files/media/NOSB%20All%20Oct%202015%20Proposals.pdf

From the Draft Guidance on Classification of Materials (NOP 5033, section 4.6 Extraction of Nonorganic Materials):[123]

> For purposes of classification of a material as synthetic or non-synthetic, a material may be classified as non-synthetic (natural) if the extraction or separation technique results in a material that meets the following criteria:
>
> • At the end of the extraction process, the material has not been transformed into a different substance via chemical change;
> • The material has not been altered into a form that does not occur in nature; and
> • Any synthetic materials used to separate, isolate, or extract the substance **have been removed from the final substance** (e.g., via evaporation, distillation, precipitation, or other means) such that they have no technical or functional effect in the final product. [emphasis added]

Sulfuric acid is added during the extraction process of both laminarin and seaweed extract. Sulfuric acid is then neutralized with sodium or potassium hydroxide. While the reaction of sulfuric acid and sodium/potassium hydroxide neutralizes the acidity, **the reaction leaves synthetic sodium sulfate or potassium sulfate. No later step in the process removes the sodium/potassium sulfate, and this remaining residue is what classifies both laminarin and seaweed extract as synthetic.**

According to the **NOSB classification guidelines**, a substance is synthetic if there are **significant residues** of a synthetic added during extraction whereas, according to the **draft NOP guidelines**, a substance is synthetic if any synthetic added during extraction is **not removed such that it has no technical or functional effect**. Unfortunately, there is still some uncertainty about which classification guidelines to use. In addition, the terms "significant" and "technical or functional effect" are not defined in either guidelines.

The minority report of spring 2014 deemed the addition of synthetic sodium and sulfur as **significant** by presenting calculations that estimated the residues in laminarin or seaweed extract. *Added* sulfate was estimated to be present at a *minimum* of 624 parts per million (ppm) and *added* sodium at 299 ppm.

The Crops Subcommittee's reasoning for classifiying laminarin as a non-synthetic and seaweed extracts as synthetic states:

> The reaction and filtration steps result in a purified Laminarin in which the sodium and sulfate ions do not have a technical or functional effect. This is quite different than the listing for aquatic plant extracts that are classified as synthetic for crop production at 205.601(j)(1). In those the extracting agents (such as potassium hydroxide) do leave behind enough potassium to have a functional effect as a fertilizer. In Laminarin, neither the sodium (at 0.001%) nor the sulfate ions (at 0.0034%) have a functional effect for disease suppression.

[123] http://www.ams.usda.gov/sites/default/files/media/NOP-5033.pdf

The minority report calculations demonstrate that the concentration of the sodium/potassium and sulfate ions in laminarin were significant and have a technical or functional effect at these concentrations as preservatives.

Crops Subcommittee deliberations and vote

Motion to classify Laminarin as petitioned as non-synthetic
Yes: 5 No: 0 Abstain: 0 Absent: Recuse: 0

Therefore, because Laminarin was classified as non-synthetic it does not need to be added to the National List.

Motion to classify Brown Seaweed Extracts as petitioned as synthetic.
Yes: 5 No: 0 Abstain: 0 Absent: 0 Recuse: 0 Listing

Motion: Motion to add Seaweed Extracts as petitioned at 205.601
Yes: 0 No: 5 Abstain: 0 Absent: 0 Recuse: 0

Human health considerations

Laminarin acts by increasing the concentration of anti-herbivore and anti-fungal metabolites in plants. This leads us to question whether laminarin and seaweed extracts **might result in levels of exposure to plant-defensive chemicals that could prove toxic to consumers**. There are sufficient issues of health and safety that the Board should evaluate as it moves forward in determining whether these materials should be recommended for allowance in organic production.

The crops for which laminarin is currently registered include tomatoes, eggplant, and cole crops (Brassicaceae), among others. Several of these plants are known to contain plant defense compounds (PDCs) that are toxic to humans. **A more thorough Technical Review of laminarin is needed to aid in the uncertainty around which PDCs are increased by application of laminarin and at what levels individual PDCs are toxic to humans**. Currently, there is still much uncertainty.

Environmental concerns

Kelp forests provide habitat, food, and shelter for many species and are highly productive and diverse. They also form important reproduction and nursery grounds for fish.[124] Although kelp itself recovers from intensive harvesting,[125] kelp harvesting can have

[124] Werner, A., & Kraan, S. (2004). Review of the potential mechanisation of kelp harvesting in Ireland. Marine Environment and Health Series, No. 17, 2004. Marine Institute.
[125] Rothman, M. D., Anderson, R. J., & Smit, A. J. (2006). The effects of harvesting of the South African kelp (Ecklonia maxima) on kelp population structure, growth rate and recruitment. *Journal of applied phycology*, *18*(3-5), 335-341.

significant impacts on other species within the ecosystem.[126]

Brown seaweed extract is a fertilizer

The Crops Subcommittee notes that although seaweed extract is petitioned as a plant "strengthener," products are labeled as a 0-0-3 or 0-0-1 fertilizer. Since brown seaweed extract is synthetic, **it is a synthetic fertilizer and should not be permitted**.

CONCLUSION

The Cornucopia Institute **opposes** the proposal by the Crops Subcommittee to classify laminarin as non-synthetic and therefore not required to be added to the National List. Our opposition is based on the synthetic extraction process and synthetic residue that remains.

Using the same rationale, we **support** the proposal of the Crops Subcommittee to classify seaweed extracts as synthetic and to deny the petition for listing on §205.601 for use as a fertilizer.

The Cornucopia Institute disagrees with the NOP draft guidance for classification of materials as "synthetic" based on the *effects* of the additives (for example, based on terms like "significant" or "technical or functional effect"). The definition of "synthetic" should be based on the method by which the material is derived.

Based on the incomplete NOP draft guidance, the Crops Subcommittee has surprisingly reached the conclusion that laminarin is non-synthetic and simultaneously decided that the very similarly made seaweed extracts are synthetic.

In addition, additional research is required to ensure that the use of laminarin will not result in the overproduction of poisonous secondary metabolites like glycoalkaloids found in solanaceous crops and glucosinolates in brassicas before their use in organic production is allowed.

[126] Lorentsen, S. H., Sjøtun, K., and Grémillet, D. (2010). Multi-trophic consequences of kelp harvest. *Biological Conservation*, *143*(9), 2054-2062.

Sulfuric Acid – Petitioned Material

SUMMARY

The Cornucopia Institute recommends **rejecting** the petition to add sulfuric acid as an allowed synthetic substance in §205.601 for use as a solubilizing agent to make micronutrients more available for plant uptake. **Sulfuric acid is dangerous to human health and the environment, is not essential for organic crop production**, and its use in manufacturing synthetic micronutrients is **inconsistent with organic practices**. The Cornucopia Institute has concerns that if sulfuric acid is allowed to manufacture micronutrients, other "quick and dirty" uses of sulfuric acid could become commonplace in organic agriculture. **Sulfuric acid is a dangerous synthetic substance and its use should be limited to industrial practices rather than organic farming.**

Rationale:

- Sulfuric acid is a **highly corrosive chemical that poses a serious risk to human health** in its use, manufacture, and incidental exposure.
- Sulfuric acid manufacture and use **contributes to acid rain**, which poses a serious **threat to freshwater ecosystems, and soil and forest health**.
- Allowing sulfuric acid to synthesize micronutrients will open the door to allowing sulfuric acid use in other ways already accepted by conventional farming.

DISCUSSION

The petitioner, BioAtlantis, Ltd., requested that sulfuric acid be approved for use in the manufacture of micronutrients with the purpose of creating a shelf-stable micronutrient product with which to feed plants. Certain micronutrients are already approved and listed in §205.601 for use in organic agriculture.

Sulfuric acid (H_2SO_4) is a commonplace industrial chemical that is used in high volume for many purposes.[127] It is used in fertilizer manufacturing (phosphate fertilizers), oil refining, mineral processing, and the chemical synthesis of other products. In conventional farming, sulfuric acid is applied to land to reclaim alkali soils.

Sulfuric acid is allowed in the manufacture of liquid fish products to adjust the pH of the fish products (citric or phosphoric acid can also be used) that are used as fertilizer in organic crop production.[128] This allowed use has a different aim than the current petition: to reduce spoilage of a sensitive product that is essential for organic crop production. The Cornucopia Institute agrees with the Crops Subcommittee that the petitioned use of sulfuric acid is ultimately intended to "spoon feed" plants micronutrients. Sulfuric acid has

[127] Sulfuric Acid. National Pollutant Inventory. Australian Government, Department of the Environment. Available at: http://www.npi.gov.au/resource/sulfuric-acid

[128] 7 CFR 205.601(j)(7) Liquid fish products—can be pH adjusted with sulfuric, citric or phosphoric acid. The amount of acid used shall not exceed the minimum needed to lower the pH to 3.5.

few uses that are not quick and dirty. Any strategies that seek to sidestep the natural processes that are the ideal in organic agriculture are inconsistent with organic practices and should not be accepted.

Technical Reports

Sulfuric acid has been **petitioned for various uses in the past**. These uses include stabilizing livestock and poultry manures for use in organic crop production, and for use in organic handling as a pH adjustment for production of seaweed extracts. Technical Reports were prepared for these petitioned uses in 2006 and 2012, respectively. Both these **petitions were rejected by the Board**.

A Technical Report was prepared for liquid fish products in 2006, but the discussion on sulfuric acid was negligible.

The 2012 Technical Report, compiled by ICF International (scientists not disclosed), details many of the human health and environmental risks associated with sulfuric acid without going into detail. The dangers sulfuric acid poses to human health and the environment should be cataloged with more specificity before this chemical is ever seriously considered for listing as an approved synthetic substance in §205.601.

Alternatives already exist

As noted by the Crops Subcommittee in their review of the petitioned substance, there are alternative options for micronutrients already on the National List:

> (6) Micronutrients—not to be used as a defoliant, herbicide, or desiccant. Those made from nitrates or chlorides are not allowed. Soil deficiency must be documented by testing.
>
> (i) Soluble boron products.
>
> (ii) Sulfates, carbonates, oxides, or silicates of zinc, copper, iron, manganese, molybdenum, selenium, and cobalt.[129]

This list includes both natural and synthetic substances.

Environmental concerns

Sulfuric acid has a negative impact on the environment. The primary sources of sulfuric acid emissions are the industries that manufacture the chemical or use it in production.[130] Sulfuric acid is also introduced into the air when sulfur dioxide is released by burning coal,

[129] 7 CFR §205.601(j)

[130] Sulfuric Acid. National Pollutant Inventory. Australian Government, Department of the Environment. Available at: http://www.npi.gov.au/resource/sulfuric-acid

oil, and gas.[131] **Sulfuric acid is easily aerosolized and will dissolve into clouds, fog, and the atmosphere in general.** The result is a very dilute acid solution that falls as "acid rain."

Acid rain has devastating effects wherever it falls. Direct rainfall and runoff will acidify freshwater lakes and streams. Acidification reduces fish and aquatic organism populations and threatens the biodiversity of any freshwater habitat.[132] Even though some wildlife is tolerant to acidic water, they may depend on other organisms in the ecosystem to survive (for example, frogs are acid-tolerant but they rely on insects that are not acid-tolerant as a food source).[133]

Acid rain also damages trees and sensitive soils.[134] With respect to trees, acid rain is linked to slower growth, injury, or death of forests.[135] This happens indirectly by damaging tree leaves and limiting the nutrients available to them. Acid rain also contributes to soil degradation as the acid dissolves essential nutrients and carries them away from the plants.[136]

Human health concerns

Exposure to sulfuric acid is associated with serious human health concerns. Sulfuric acid is a powerful and corrosive chemical that **can cause third degree burns and blindness on contact**.[137] Exposure to sulfuric acid is associated with a number of other health risks besides contact burns, including **dental erosion, pulmonary fibrosis, bronchiectasis, and emphysema**.[138] At lower concentrations sulfuric acid is known to cause **eye, nose, throat, bronchial, and skin irritation**.[139]

Sulfuric acid is a known human carcinogen. The International Agency for Research on Cancer has confirmed that exposure to sulfuric acid mist causes increased occurrence of laryngeal and lung cancer.[140] Exposure to sulfuric acid mist in the short term can irritate

[131] Public Health Statement for Sulfur Trioxide and Sulfuric Acid, December 2008. Agency for Toxic Substances and Disease Registry. Available at: http://www.atsdr.cdc.gov/phs/phs.asp?id=254&tid=47
[132] Effects of Acid Rain - Surface Waters and Aquatic Animals. US Environmental Protection Agency. Available at: http://www3.epa.gov/acidrain/effects/surface_water.html
[133] Ibid.
[134] Effects of Acid Rain. US Environmental Protection Agency. Available at: http://www3.epa.gov/acidrain/effects/
[135] Effects of Acid Rain – Forests. US Environmental Protection Agency. Available at: http://www3.epa.gov/acidrain/effects/forests.html
[136] Ibid.
[137] Sulfuric Acid. National Pollutant Inventory. Australian Government, Department of the Environment. Available at: http://www.npi.gov.au/resource/sulfuric-acid
[138] Sulfuric Acid. Occupational Safety & Health Administration, United States Department of Labor. Available at: https://www.osha.gov/dts/chemicalsampling/data/CH_268700.html
[139] Ibid.
[140] Occupational Exposures to Mists and Vapours From Sulfuric Acid and Other Strong Inorganic Acids. International Agency for Research on Cancer (IARC) - Summaries & Evaluations. Document available at: http://www.inchem.org/documents/iarc/vol54/01-mists.html

the entire respiratory system and even lead to pulmonary edema.[141]

Acid rain is also a factor in human health that needs to be considered beyond its environmental impacts. As an indirect risk to human welfare, this rain accelerates the decay building and infrastructure materials.[142] While acid rain does not have a direct impact on human health (it is safe to walk in acid rain), the pollutants that cause acid rain, including sulfuric acid, do damage human health. Fine particles of sulfate pollutants can be carried by winds and rain and inhaled. Scientific studies have identified a relationship between elevated levels of these fine particles and increased illness and death from heart and lung disorders (such as asthma and bronchitis).[143]

Approval of the petitioned use opens the door to other sulfuric acid uses

The Cornucopia Institute is concerned that if sulfuric acid is approved for use in micronutrient products, its use in other areas of organic agriculture will be approved in short order or overlooked. One of these uses is very common in conventional farming practices: the use of sulfuric acid to reclaim alkali soils. This practice has many parallels to the petitioned use because it also has the **effect of circumventing natural biological processes of enhancing soil fertility**.

Soils with high alkalinity need some kind of soil amendment to lower the pH to make the soil suitable for planting, as most crops prefer a soil pH closer to neutral or even slightly acidic. There are many ways to reclaim alkaline soil. Methods already accepted in organic agriculture include the use of elemental sulfur and sulfurous acid in irrigation water. The decomposition of organic matter (usually from compost) also adds to soil acidity.[144]

Elemental sulfur is on the National List as insecticides[145] (including acaricides or mite control), as plant disease control,[146] and as a plant or soil amendment.[147] Adding elemental sulfur to an alkaline soil has a greater effect on soil pH than using compost, but can also be slow if conditions are not right. Sulfur is oxidized by bacteria to form sulfuric acid which then binds with salts and free lime to lower soil pH.[148] Using elemental sulfur to amend acid soils is a slow process that requires bacterial activity, frequent irrigation, and constant monitoring. These steps may be more cost and labor intensive for some farmers, making a "quick fix" seem attractive. However, supporting soil microbes and working within natural processes is an important aspect of organic agriculture and critical to the integrity of the organic label.

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[141] Sulfuric Acid. National Pollutant Inventory. Australian Government, Department of the Environment. *Available at:* http://www.npi.gov.au/resource/sulfuric-acid
[142] Effects of Acid Rain - Human Health. US Environmental Protection Agency. *Available at:* http://www3.epa.gov/acidrain/effects/health.html
[143] Ibid.
[144] Sulfuric Acid Agricultural Data Sheet , Verdegaal Brothers, Inc.
[145] 7 CFR §205.601(e)(5)
[146] 7 CFR §205.601(i)(10)
[147] 7 CFR §205.601 (j)(2)
[148] http://cesanluisobispo.ucanr.edu/files/152040.pdf

Sulfurous acid is created by burning elemental sulfur and incorporating it with irrigation water to create sulfurous acid. Sulfurous acid is currently on the National List[149] as a synthetic substance allowed for use in organic crop production when it is generated on-farm using elemental sulfur. A Technical Report for sulfurous acid was prepared in 2014.[150] To create sulfurous acid, many farmers use sulfur burners. These units work by burning a solid form of sulfur to produce sulfur dioxide. Sulfur dioxide reacts with water to form sulfurous aid (H_2SO_3). Sulfurous acid and sulfuric acid have similar effects on soil and water, but sulfurous acid is considered a safer alternative. Sulfurous acid is safer to handle and does not carry the same negative implications for environmental health that sulfuric acid does.

In conventional farming sulfuric acid is commonly used as a soil corrective in reclamation for sodic soils containing a significant amount undissolved lime ($CaCO_3$).[151] These soils often have high levels of sodium as well, which adds to the problem of alkalinity.[152] Calcareous soils that have high levels of calcium carbonate are self-buffering such that lowering the pH of irrigation water will do little to adjust the long-term alkalinity of the soil.[153] Sulfuric acid has been found to have a significant effect on the sodic *soil, even when used in combination with other reclamation efforts*.[154]

Unfortunately, the conventional method of applying sulfuric acid directly to the soil comes at a high cost. The process does not take into account overall soil health and circumvents natural soil processes of decomposition and microbe action. As already discussed, there are serious human and environmental health considerations associated with sulfuric acid. Applying the acid to the soil requires experienced handlers and equipment as incidental exposure to the acid is a serious risk.[155]

The treatment of soil with elemental sulfur and sulfuric acid differ in the time required for the biological oxidation of the elemental sulfur and the functional process of application.[156]

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[149] 7 CFR § 205.601(j)(9) Sulfurous acid (CAS # 7782-99-2) for on-farm generation of substance utilizing 99% purity elemental sulfur per paragraph (j)(2) of this section.

[150] http://www.ams.usda.gov/sites/default/files/media/Sulfurous%20Acid%20TR%202014.pdf

[151] Sulfur Information Service. Soil Amendments. Accessed September 23, 2015. Available at: http://sulfur.nigc.ir/en/sulfuruses/agricultural/sulfuramendments/soilamendments#Sulfuric

[152] Sulfuric Acid Agricultural Data Sheet , Verdegaal Brothers, Inc. http://www.verdegaalbrothers.com/data-sheets/sulfuric-acid.pdf

[153] Uses of Sulfuric Acid as a Water Amendment in Agriculture, by James R. Gregory. Presented at the International Irrigation Show, San Antonio, Texas. November 4, 2001. http://crusty.integritynet.com/ph_meters/Uses_of_sulfuric_acid_as_water_admendment.pdf

[154] Majid Mahmoodabadi, Najme Yazdanpanah, Leonor Rodríguez Sinobas, Ebrahim Pazira, Ali Neshat. Reclamation of calcareous saline sodic soil with different amendments (I): Redistribution of soluble cations within the soil profile. Agricultural Water Management, Volume 120, 31 March 2013, Pages 30–38. Soil and Irrigation Sustainability Practices. Available at: http://www.sciencedirect.com/science/article/pii/S0378377412002326

[155] Uses of Sulfuric Acid as a Water Amendment in Agriculture, by James R. Gregory. Presented at the International Irrigation Show, San Antonio, Texas. November 4, 2001. http://crusty.integritynet.com/ph_meters/Uses_of_sulfuric_acid_as_water_admendment.pdf

[156] Sulfur Information Service. Soil Amendments. Accessed September 23, 2015. Available at: http://sulfur.nigc.ir/en/sulfuruses/agricultural/sulfuramendments/soilamendments#Sulfuric

Compared to elemental sulfur amendments, application of sulfuric acid circumvents both the time commitment and the need for ideal conditions for microbes.[157] This circumvention would add a level of synthetic operation to soil reclamation that is not compatible with organic agriculture.

Action by the Crops Subcommittee

The Crops Subcommittee has reservations toward the petitioned use of sulfuric acid. Specifically, the subcommittee notes that "the process of treating micronutrients with Sulfuric Acid as described in this petition will produce forms of micronutrients that are highly refined and designed to spoon-feed plants in ways that circumvent the natural soil biological processes central to organic farming systems, as described in the organic standards definition of organic production (205.2): 'A production system that …[integrates] cultural, biological, and mechanical practices that foster cycling of resources, promote ecological balance, and conserve biodiversity.'"

The Crops Subcommittee voted to list Sulfuric Acid, as petitioned, at §205.601 as follows: Yes: 0 No: 5 Abstain: 0 Absent: 0 Recuse: 0

CONCLUSION

The Cornucopia Institute joins the Crops Subcommittee in recommending that the NOSB **reject the petition to add sulfuric acid** as an allowed synthetic substance to §205.601 for use as a solubilizing agent for plant micronutrients because it fails all three OFPA criteria.

There are concerns that accepting this petition may lead to the expanded use of sulfuric acid in other areas of organic agriculture. Specifically, Cornucopia has concerns that sulfuric acid will someday be allowed as a direct soil amendment as is common in conventional farming. While sulfuric acid may have beneficial applications for specific soil and crop types, sulfuric acid speeds up a process that would otherwise take the work of soil microorganisms and other, safer, methods of soil reclamation. If sulfuric acid is used as a solubilizing agent it supports highly manufactured processes that do not take into account the importance of holistic approaches to soil and plant health essential to organic agriculture.

[157] *Managing High pH, Calcareous, Saline, and Sodic Soils of the Western Pecan Growing Region*, by GS Sibbett (1995). http://horttech.ashspublications.org/content/5/3/222.full.pdf

HANDLING SUBCOMMITTEE

2017 SUNSET MATERIALS

Celery Powder

SUMMARY

The Cornucopia Institute **stands** neutral as to the relisting of celery powder under §205.606(b); however, Cornucopia supports the reclassification of celery powder to §205.605(b*)* Synthetics allowed.

In addition, The Cornucopia Institute strongly calls for additional research to develop a viable organic alternative with**in the next five** years.

Rationale:

- Celery powder produced via a chemical-intensive agriculture contains artificially induced high levels of nitrates from synthetic sources and should be considered a synthetic compound.
- The evaluation of celery powder must take into consideration the resulting health and environmental hazards associated with the use of pesticides in the non-organic production of celery.
- Nitrates and nitrites have known negative health effects.
- Its use may be a direct violation of OFPA and the **o**rganic regulations.
- The current availability of organic celery for the production of celery powder must be further investigated.
- The potential commercial availability for organic celery powder must be evaluated if a demand existed.
- No TR was ever compiled for celery powder**. A** TR would help assess the safety of celery powder and the availability of a viable alternative, organic or not.

DISCUSSION

Celery powder: a source of nitrates for curing meats

Synthetic nitrates or nitrites are commonly used to cure meats, but when nitrates are used, they are converted to nitrites, which actually provide the curing action. Nitrates/nitrites are used in cured meat products for flavor and appearance and to preserve and extend shelf life. They also inhibit the growth of *Clostridium botulinum*, *Listeria monocytogenes***,** and other pathogenic organisms responsible for food poisoning. Synthetic nitrates are not allowed in organic production, so celery powder is used as an alternative.

Celery is one of many vegetables that are naturally high in nitrates (they accumulate nitrates efficiently in their tissues). When used in organic processing (**the** curing of meat), the nitrates in the celery powder are converted to nitrites by a lactic acid starter culture.

The product is typically standardized to a guaranteed part per million nitrite content. Thus the cultured celery powder is a way of adding "natural" nitrites. The quotation marks indicate that the nitrites are not really natural since they come from conventional celery, grown using intentionally high levels of synthetic nitrogen fertilizers.

Essentiality and alternatives

Lactic acid**,** as well as sodium and potassium lactates**, are some of the few anti**microbial compounds accepted by the FDA that can replace nitrates/nitrites in meat products and are GRAS.[158]

According to the industry (Applegate, Coleman Natural, Organic Valley), it has not been possible so far to achieve the high levels of nitrate needed through organic celery production.[159]

However, a recent study showed that equivalent amounts of nitrates have been found in organic celery as compared to celery **obtained via a chemical-**intensive agriculture.[160] This demonstrates that it might be quite feasible to develop a variety of celery suitable for organic production and capable of providing the levels of nitrates necessary for use in meat processing.

In their comments, CROPP**/Organic Valley**, Coleman Natural Foods**,** and Applegate supported the relisting of celery powder, citing lack of alternatives (whether organic or not), the need for more research to develop a viable organic alternative, the resulting disappearance of many certified organic processed meat products from the market, and ensuing economic hardship if removed from the National List.

Environmental and human health concerns

Production of celery by a chemical-intensive agriculture, with especially high levels of nitrogen applications, leads to the contamination of streams and groundwater, and impacts wildlife. Several of the pesticides used in conventional celery production are toxic to honey bees and other pollinators.[161]

As explained in the previous section, celery powder is used in such a way that it adds significant nitrite, as illustrated by the following excerpt:

> Celery powder prepared from celery juice has been shown to have a nitrate content of approximately 2.75%. When using juice powder added at 0.2%, 0.35%, or 0.4% (on a total formulation basis), and assuming 100% nitrate-to-nitrite conversion, ingoing nitrite concentrations of approximately 69, 120, and 139 ppm (based on meat block), respectively, could be expected. As the amount of celery juice powder in the

[158] 2015 TR – Lactic acid and lactates. Page 5, lines 171-179

[159] J.J. Sindelar and T.A. Houser, Alternative Curing Systems, in Tarté, R. (Ed.). (2009). *Ingredients in meat products: properties, functionality and applications*. Springer Science & Business Media. pp. 398–399.

[160] https://www.academia.edu/3428238/comparative_study_on_mineral_content_of_organic_and_conventional_carrot_celery_and_red_beet_juices

[161] http://www.beyondpesticides.org/resources/eating-with-a-conscience/choose-a-crop?foodid=12

> formulation increases, higher amounts of generated nitrite can be expected. From these results it was determined an uncured product with nitrite replaced with a source containing naturally occurring nitrate could result in a product with higher levels of residual nitrite than one in which nitrite was originally and intentionally added.[162]

The concentrations above should be compared to the limit of 10 ppm in drinking water and the European Commission's (EC) Scientific Committee for Food (SCF) Acceptable Daily Intake (ADI) for the nitrate ion of 3.65 mg/kg body weight (equivalent to 219 mg/day for a 60 kg person).

The ATSDR/CDC (Agency for Toxic Substances & Disease Registry/Center for Disease Control) lists, for example, methemoglobinemia, hypotension, risk of pregnancy complications, a number of reproductive effects, and cancer, among others. Regarding cancer, ATSDR notes:

> Some study results have raised concern about the cancer-causing potential of nitrates and nitrites used as preservatives and color-enhancing agents in meats [Norat et al. 2005; Tricker and Preussmann 1991]. Nitrates can react with amino acids to form nitrosamines, which have been reported to cause cancer in animals [Bruning-Fann and Kaneene 1993]. Elevated risk of non-Hodgkin's lymphoma [Ward et al. 1996] and cancers of the esophagus, nasopharynx, bladder, colon, prostate and thyroid have been reported [Cantor 1997; Eichholzer and Gutzwiller 1998; Barrett et al. 1998; Ward et al. 2010].
>
> An increased incidence of stomach cancer was observed in one group of workers with occupational exposures to nitrate fertilizer; however, the weight of evidence for gastric cancer causation is mixed [Van Loon et al. 1998; Xu et al. 1992]. Epidemiological investigations and human toxicological studies have not shown an unequivocal relationship between nitrate intake and the risk of cancer [Alexander et al. 2010; Mensinga et al. 2003].
>
> The International Agency for Research on Cancer (IARC) classifies nitrates and nitrites as "probably carcinogenic to humans" (Group 2A) under certain conditions (i.e. ingested nitrate or nitrite under conditions that result in endogenous nitrosation) which could lead to the formation of known carcinogens such as N-nitroso compounds [IARC 2010].

Finally, recent work demonstrates serious hormonal impacts of nitrate exposure.[163,164]

However, none of the comments in support of celery powder mentioned the known negative health effects associated with dietary i**ntake of nitrates and nitrites;** thus it could be argued that the arguments presented did not provide sufficiently compelling

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[162] *Ingredients in Meat Products: Properties, Functionality and Applications*. pp. 398–399**.**

[163] Guillette, L. J., & Edwards, T. M. (2005). Is nitrate an ecologically relevant endocrine disruptor in vertebrates?. *Integrative and Comparative Biology*, *45*(1), 19-27**.**

[164] Guillette, L. J. (2006). Endocrine disrupting contaminants-beyond the dogma. *Environmental health perspectives*, *114*, 9**.**

reasons for keeping celery powder on the National List.

Compatibility with OFPA

§205.600(b)(4) states: "*The substance's primary use is not as a preservative or to recreate or improve flavors, colors, textures, or nutritive value lost during processing, except where the replacement of nutrients is required by law*."

Accordingly, celery powder should be used only for its potential **antimicrobial activity** and not to improve the flavor, color**,** or texture of meat products.

OFPA §6510(a)(2)-(3) makes it *illegal to*:

(1) *add* any *synthetic ingredient* not appearing on the National List during the processing or any postharvest handling of the product;
(2) *add* any ingredient known to contain levels of *nitrates*, heavy metals, or toxic residues in excess of those permitted by the applicable organic certification program;
(3) *add* any sulfites, except in the production of wine, *nitrates, or nitrites*;

The regulations at §205.301(f)(5) state that organic products must not **"**Contain sulfites, nitrates, or nitrites added during the production or handling process, Except, that, wine containing added sulfites may be labeled 'made with organic grapes'."

These regulations clearly demonstrate that the addition of nitrates or nitrites is illegal in organic production.

Considering that celery powder is obtained through a chemical-intensive agriculture containing high levels of nitrates provided by synthetic fertilizers, it could be argued that such an ingredient is synthetic, making it illegal per OFPA regulations.

Handling Subcommittee deliberations and vote

The Handling Subcommittee reviewed the history of celery powder use, and mentioned some of the comments received at the Spring 2015 NOSB meeting. Health or potential environmental concerns were not addressed.

<u>Vote:</u>

Motion to remove celery powder from 205.606(b)
Motion by: Tom Chapman
Seconded by: Ashley Swaffar
Yes: 1 No: 6 Abstain: 0 Absent: 0 Recuse: 0

CONCLUSION

In light of the apparent lack of viable alternatives, and potential hardship to organic farmers, The Cornucopia Institute **stands** neutral as to the relisting of celery powder under §205.606(b); however, Cornucopia supports the reclassification of celery powder to §205.605(b*)* Synthetics allowed. It is unlikely that Cornucopia will take a neutral position when **c**elery **p**owder is reviewed during its next **s**unset.

The use of celery powder is a way of artificially boosting nitrate amounts for use as a preservative at levels not currently possible to achieve through use of organic celery.[165] Nitrates pose dangers to health when artificially enhanced in food.

Therefore**,** The Cornucopia Institute strongly calls for a full Technical Review, to better evaluate this material, **and** additional research to develop a viable organic alternative within the next **five** years.

[165] Martignon, G., Casarotti, D., Venezia, A., and Malorgio, F. (1994). Nitrate accumulation in celery as affected by growing system and n content in the nutrient solution. Acta Hortic. 361, 583-589

Chlorine Materials

SUMMARY

The Cornucopia Institute **remains neutral in the relisting of all chlorine materials at §205.601, §205.603, and §205.605**, specifically **calcium hypochlorite, sodium hypochlorite, and chlorine dioxide** for use as algicides, disinfectants, and sanitizers, for medical treatments as applicable, and for disinfecting and sanitizing facilities and equipment, including cleaning irrigation systems. Chlorine materials are also listed for pre-harvest use, where residual chlorine levels in the water must not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (SDWA).[166]

Cornucopia recommends that the NOSB and NOP eliminate the use of chlorine-based materials and develop guidance for the adoption and appropriate usage of alternative materials and practices. **The NOSB subcommittees should commission a TR that (1) determines what disinfectant/sanitizer uses are required by law, and (2) comprehensively reviews more organically compatible methods and materials to determine whether chlorine-based materials are actually needed for any specific purposes.** If there are uses for which chlorine materials are necessary, then the NOSB should include them on the National List, as restricted-use materials, and limit them to those particular applications.

Rationale:

- Chlorine materials are harmful to the environment. Disinfection with chlorine, hypochlorite, or chloramines results in the formation of carcinogenic trihalomethanes, haloacetic acids, and other toxic byproducts. Disinfection with chlorine dioxide produces undesirable inorganic byproducts, chlorite and chlorate.
- Calcium hypochlorite and sodium hypochlorite are highly caustic and are a concern for occupational exposures. Chlorine dioxide is a severe respiratory and eye irritant, and inhalation of chlorine dioxide can cause nose, throat, and lung irritation.
- Safer alternatives exist, including citric acid, hydrogen peroxide, l-lactic acid, ethanol, isopropanol, peracetic acid, and ozone. The safest of these, lactic acid and citric acid, are both considered non-synthetic and are listed on §205.605(a) with no restrictions as to their use.

[166] EPA. 2009. List of Contaminants & their MCLs. Available at: http://water.epa.gov/drink/contaminants/index.cfm#List.

DISCUSSION

Table 1: Comparison of Chlorine Compounds

Compound	Calcium Hypochlorite	Sodium Hypochlorite	Chlorine Dioxide
Properties	• $CaCl^2O^2$ • "Powdered Bleach" • FDA considers an "indirect food additive" • Kills microorganisms indirectly by inactivating an essential enzyme needed for digestion of glucose • Sold as a powder, stores for a long time	• ClNaO • "Liquid Bleach" • FDA considers an "indirect food additive" • Kills microorganisms indirectly by inactivating an essential enzyme needed for digestion of glucose • Sold as a liquid	• ClO_2 • FDA allows as a "direct food additive" at certain levels • Kills microorganisms directly by disrupting nutrient transport across cell walls • Sold as gas or liquid; must be made on site by combining sodium chlorite with an acid
Effective Against	• Bacteria • Fungi • Slime-forming algae	• Bacteria • Fungi • Slime-forming algae	• Giardia • Viruses • Cysts • Algae • E. coli • Staph • Salmonella
Advantages	• More stable than sodium hypochlorite • Release more available chlorine than sodium hypochlorite	• Broad-spectrum disinfectant • Readily available, most common form of bleach	• More soluble in water; thus, more often used to disinfect water systems • Removes odors and taste of decaying vegetation; also does not have "bleach" smell • Prevents the formation of biofilms in water treatment systems • More effective and less corrosive than chlorine[167] • The application of chlorine dioxide does not produce halogenated DBPs (like THMs) and produces only a small amount of total organic halides (TOX)[168,169]

[167] EPA. 1999b. Chapter 4. Chlorine Dioxide. Available at: http://www.epa.gov/safewater/mdbp/pdf/alter/chapt_4.pdf

[168] Werdehoff, K.S. and P.C. Singer. (1987). Chlorine Dioxide Effects on THMFP, TOXFP, and the Formation of Inorganic Byproducts. *Journal of American Water Works Association*. 79(9): 107-113.

			• Effective over wide range of temperatures and pHs (2-10 pH) • Recent data suggest that aqueous chlorine dioxide is equally suitable to sodium hypochlorite for fresh-cut lettuce sanitation with the advantage of preventing the formation of THMs[170] • Effective over a wide range of temperatures and pHs
Disadvantages	• Imparts bad "bleachy" taste in water • Adds calcium and can cause scaling (calcium build-up) • Can be hard to mix properly and can clog sprayers • Produces toxic disinfection byproducts such as THMs • Less effective in alkaline (hard) waters or water contaminated with high organic material loads	• Imparts bad "bleachy" taste in water • Produces toxic disinfection byproducts such as THMs • Less effective in alkaline waters or water contaminated with high organic material loads	• Less effective than ozone[171] • Cannot be shipped in a drum; must be produced on site

Chlorine materials used for disinfection are listed in three places on the National List, all of which are subject to 2017 sunset:

> §205.601 (a) As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems. (2) Chlorine materials—For pre-harvest use, residual chlorine levels in the water in direct crop contact or as water from cleaning irrigation systems applied to soil must not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act, except that chlorine products may be used in edible sprout production according to EPA label directions.
> (i) Calcium hypochlorite.

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[169] Lopez-Galvez, F., A. Allende, P. Truchado, A. Martinez-Sanchez, J.A. Tudela, M.V. Selma, M.I. Gil. (2010). Suitability of aqueous chlorine dioxide versus sodium hypochlorite as an effective sanitizer for preserving quality of fresh-cut lettuce while avoiding byproduct formation. *Postharvest Biology and Technology*. 5(1): 53-60.
[170] Lopez-Galvez, F., A. Allende, P. Truchado, A. Martinez-Sanchez, J.A. Tudela, M.V. Selma, M.I. Gil. (2010). Suitability of aqueous chlorine dioxide versus sodium hypochlorite as an effective sanitizer for preserving quality of fresh-cut lettuce while avoiding byproduct formation. *Postharvest Biology and Technology*. 5(1): 53-60.
[171] EPA. 1999b. Chapter 4. Chlorine Dioxide. Available at: http://www.epa.gov/safewater/mdbp/pdf/alter/chapt_4.pdf

(ii) Chlorine dioxide.
(iii) Sodium hypochlorite.

§205.603 (a) As disinfectants, sanitizer, and medical treatments as applicable. (7) Chlorine materials—disinfecting and sanitizing facilities and equipment. Residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.
(i) Calcium hypochlorite.
(ii) Chlorine dioxide.
(iii) Sodium hypochlorite.

§205.605(b) Chlorine materials—disinfecting and sanitizing food contact surfaces, *Except,* that, residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (Calcium hypochlorite; Chlorine dioxide; and Sodium hypochlorite).

[Handling] §205.605(b) Acidified sodium chlorite—Secondary direct antimicrobial food treatment and indirect food contact surface sanitizing. Acidified with citric acid only.

Chlorine materials were added to the National List in 1995 without petition and have been relisted in subsequent sunsets. Calcium hypochlorite, sodium hypochlorite, and chlorine dioxide are all synthetic materials that are manufactured by chemical processes and are not extracted from naturally occurring sources. Chlorine is the second-most reactive element (after fluorine) in the halogen series. Halogens bond with hydrogen to form acids and are generally toxic. The middle halogens—chlorine, bromine, and iodine—are often used as disinfectants.[172]

Chlorine is a strong oxidizer so does not occur naturally in its pure (gaseous) form. Nearly all naturally occurring chlorine occurs as chloride, the ionic form found in salts such as sodium chloride. Chloride (the ionic form of chlorine) occurs naturally and is necessary for life. Gaseous chlorine is formed by running an electric current through salt brine.[173]

In the past, we have seen some confusion over the terminology used to describe chlorine in treated water. This description may help:

> Reactive chlorine (RC) is the combined concentration of various chlorine species able to react and interconvert in a given system. It is essentially synonymous with total residual chlorine (TRC), combined residual chlorine (CRC), and total available chlorine (TAC). It includes free available chlorine (FAC; hypochlorous acid [HOCl] and the hypochlorite ion [OCl]; also referred to as free residual chlorine [FRC]) and

[172] http://en.wikipedia.org/wiki/Halogen
[173] http://en.wikipedia.org/wiki/Chlorine

combined available chlorine (CAC; organic and inorganic chloramines [NH_2Cl, $NHCl_2$, and NCl_3] or N-chloramides).[174]

The high oxidizing potential of chlorine leads to its use for bleaching, in biocides, and as a chemical reagent in manufacturing processes. Because of its reactivity, chlorine and many of its compounds bind with organic matter. In the case of bleaches, the reaction with chlorine destroys chemicals responsible for color. When used as a disinfectant, chlorine reacts with microorganisms and other organic materials. Similarly, the toxicity of chlorine to other organisms comes from its power to oxidize cells.

Synthetic chlorine compounds may be inert—in which case the chlorine is responsible for toxicity and a lack of biodegradability. Chlorinated organic compounds include pesticides ranging from DDT to 2,4-D. Chlorine gas was the first poison gas used in warfare. The largest use of chlorine is in the manufacture of polyvinyl chloride (PVC).

Chlorine gas reacts with water to produce hydrochloric acid (HCl), hypochlorous acid (HOCl), and hypochlorite (OCl^-). When hypochlorous acid reacts with ammonia, it forms chloramines, which are reactive enough to be used as disinfectants, but are more stable than hypochlorous acid and hypochlorite.

Calcium hypochlorite ($CaCl_2O_2$) and sodium hypochlorite (ClNaO) are both known as bleach and have similar properties. Their minor differences are explained in Table 1, above. Sodium and calcium hypochlorite are chlorinated inorganic disinfectants used to control bacteria, fungi, and slime-forming algae that can cause diseases in people and animals.[175] These disinfectants also are used in cleaning irrigation, drinking water, and other water and wastewater systems.

Chlorine dioxide (an extremely toxic and potentially explosive gas) is produced by reacting sodium chlorate with a suitable reducing agent in a strongly acidic solution. Sodium chlorite may be produced from the chlorine dioxide solution under alkaline conditions using hydrogen peroxide. Acidifying the sodium chlorite solution produces chlorine dioxide for disinfection.

Chlorine dioxide (ClO_2) is an antimicrobial disinfectant and pesticide used to control harmful microorganisms including bacteria, viruses, and fungi on inanimate objects and surfaces primarily in indoor environments. It is used in cleaning water systems and disinfecting public drinking water supplies.[176] It also is used as a bleaching agent in paper and textile manufacturing, as a food disinfectant (e.g., for fruit, vegetables, meat, and

[174] Canadian Environmental Quality Guidelines Canadian Council of Ministers of the Environment, 1999. Canadian Water Quality Guidelines for the Protection of Aquatic Life: Reactive Chlorine Species, p. 1. http://ceqg-rcqe.ccme.ca/download/en/208

[175] EPA. 1991. R.E.D. Facts. Sodium and Calcium Hypochlorite Salts. Available at: http://www.epa.gov/oppsrrd1/REDs/factsheets/0029fact.pdf.

[176] http://www.atsdr.cdc.gov/toxprofiles/tp.asp?id=582&tid=108

poultry), for disinfecting food processing equipment, and for treating medical wastes, among other uses.[177]

The manufacture of toxic chlorine compounds results in the unintended production of other toxic chemicals. **Disinfection with chlorine, hypochlorite, or chloramines results in the formation of carcinogenic trihalomethanes, haloacetic acids, and other toxic chlorinated byproducts.**[178] Disinfection with chlorine dioxide produces undesirable inorganic byproducts, chlorite and chlorate. Industrial production of chlorine compounds, use of chlorine bleach in paper production, and the burning of chlorine compounds releases chlorinated dioxins and other persistent toxic chemicals into the environment.[179]

The difference between chloride compounds and the toxic products and byproducts of the chlorine chemical industry are that almost all of the former are naturally occurring materials that do not share the toxic persistence of the latter. **The fact that the use of chlorine is so universally associated with the production of persistent toxic chemicals has led some environmental groups to seek a ban on chlorine-based chemicals.** Likewise, organic production would be better served by avoiding the use of chlorine when possible.

The allowance of chlorine in the rule reflects the fact that many growers depend on water sources that have been treated with chlorine. Organic producers should not have to filter chlorine out of the tap water they use for irrigating, cleaning equipment, washing vegetables, or cleaning food-contact surfaces. But additional chlorine usage requirements are questionably necessary. To fulfill the mandate of not doing environmental harm, **organic production and handling should be, to the extent possible, chlorine-free**.

Human health and environmental concerns

Calcium hypochlorite, chlorine dioxide, and sodium hypochlorite can be harmful to human health and the environment. In water and soil, sodium and calcium hypochlorite separate into sodium, calcium, and hypochlorite ions, and hydrochlorous acid molecules. Hydrochlorous acid molecules diffuse through the cell walls of bacteria, changing the oxidation-reduction potential of the cell, inactivating enzymes and destroying the cell's ability to function. Chlorine dioxide kills cells directly by disrupting the transport of nutrients across cell walls.

Calcium hypochlorite and sodium hypochlorite are highly caustic and are a concern for occupational exposures. Acute exposure to high concentrations can case eye and skin injury; ingestion can cause gastrointestinal irritation and corrosive injuries to the mouth,

[177] EPA. 2003. Pesticides: Topical & Chemical Fact Sheets. Chlorine Dioxide. http://www.epa.gov/pesticides/factsheets/chemicals/chlorinedioxidefactsheet.htm
[178] Alexander G. Schauss, 1996. Chloride – Chlorine, What's the difference? P. 4. http://www.mineralresourcesint.com/docs/research/chlorine-chloride.pdf
[179] ATSDR, 1998. Toxicological Profile for Chlorinated Dibenzo-p-Dioxins. Pp. 369 ff. http://www.atsdr.cdc.gov/toxprofiles/tp104.pdf

throat, esophagus, and stomach. Chlorine dioxide is a severe respiratory and eye irritant, and inhalation of chlorine dioxide can cause nose, throat, and lung irritation. Chlorate, the reaction product of chlorine dioxide, can cause oxidative damage to red blood cells.[180] "Off gassing" by activating dilute aqueous solutions of sodium chlorite with an acid to produce chlorine dioxide can be a safety hazard to users.

Chlorine materials are **highly toxic to freshwater fish and invertebrates**. Sodium hypochlorite has the potential to raise soil pH and add sodium to the soil. When released to water or soil, one of the reaction products of sodium and calcium hypochlorite is hypochlorite ions. When mixed with organic materials (e.g., dirt), hypochlorite produces trihalomethanes (THMs), which are carcinogenic. There is a slightly increased risk of developing bladder or colorectal cancer over a lifetime if trihalomethanes are ingested in excess of the current drinking water limits over an extended period of time. The EPA has ruled that concentrations of trihalomethanes in water should be less than 80 parts per billion (ppb). Other chlorine disinfectant byproducts include haloacetic acids (HAAs), chlorites, and bromates.

The 2006 Technical Report is <u>woefully inadequate</u> with regards to discussing the environmental concerns of both the manufacture of chlorinated compounds, the use of these products for livestock production, and the environmental fate or impact of the waste or disposal products after use.

Manufacturers who use chlorine bleach often release it into local water bodies or water treatment systems along with other liquid industrial waste. Once it reaches the water, chlorine (hypochlorite) **reacts with other minerals and organic materials to form a host of dangerous toxins**. These toxins, including dioxins, furans, and THMs, are often referred to as "persistent organic pollutants" because they remain in the water or soil and take many years to disappear. **Greenpeace calls chlorinated dioxin one of the most dangerous chemicals known to science and warns that it can contribute to cancer, endocrine disorders, and other serious health effects**.

These chlorinated compounds are highly reactive and are broken down by sunlight to compounds commonly found in the air. In water and soil, sodium and calcium hypochlorite separate into sodium, calcium, hypochlorite ions, and hypochlorous acid molecules. **The TR states that calcium hypochlorite and sodium hypochlorite are not bio-accumulative; yet when chlorine products react with other minerals or organic matter, they produce <u>persistent organic pollutants</u>. In addition (and not mentioned in the TR), mercury cell electrolysis (a common production method) of chlorine is also a <u>huge contributor to mercury pollution</u>—some estimates rank it as high as coal-fired power plants.[181]**

[180] http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5087947&acct=nopgeninfo

[181] Oceana. 2005. Poison Plants: Chlorine Factories are a Major Global Source of Mercury. Accessed March 13, 2015 here: http://oceana.org/sites/default/files/reports/PoisonPlants1.pdf

Although sodium and calcium hypochlorite are low in toxicity to avian wildlife, they are highly toxic to freshwater fish and invertebrates. The National Organic Program Rule states that the amount of calcium hypochlorite/sodium hypochlorite must be limited so that flush water from organic processing or livestock facilities and equipment does not exceed the maximum residual disinfectant limit of chlorine under the Safe Drinking Water Act (i.e., 4 mg of chlorine/L). However, the question remains: **how can livestock producers ensure that only the allowed concentrations of chlorine compounds are in the wastewater/runoff coming off their facilities?**

Calcium hypochlorite and sodium hypochlorite are highly caustic and are a concern for occupational exposures. Acute exposure to high concentrations of these compounds can cause eye and skin injury; ingestion can cause gastrointestinal irritation and corrosive injuries to the mouth, throat, esophagus, and stomach. A study conducted in Cyprus showed that women had higher levels of THMs in their urine due to their exposure to disinfection byproducts (DBPs) from washing dishes, mopping, and toilet cleaning with chlorinated substances.[182] These are similar to the types of activities you might find in an organic processing or livestock facility using chlorinated compounds for disinfecting equipment, washing livestock housing, water bowls, mopping stall floors, etc.

Inhaling warm, chlorinated water has been shown to elevate THM accumulation risks as well.[183] Therefore, a dairy farm employee using a warm water spray in the milking facility or equipment in the milk house will have elevated risks. Likewise, an employee of an organic processor having to wash down the walls or production surfaces of a food processing room will be at risk. The animals too will have the same risks for inhalation, dermal, and ingestion exposure to DBPs.

Epidemiological studies published in the last 10 years have reported **increased risks of bladder, colorectal, and renal cancer, and adverse reproductive and developmental outcomes** in people exposed to chlorinated drinking water or DPBs, although not consistently.[184] In general, there is considerably more scientific evidence that chlorinated compounds produce toxic DBPs that are human and livestock health concerns. **The TRs barely mention these health consequences and thus should be updated with the latest science.**

Chlorine dioxide is a severe respiratory and eye irritant, and inhalation of chlorine dioxide can cause nose, throat, and lung irritation. The reaction product of chlorine dioxide, chlorate, can cause oxidative damage to red blood cells (2006 TR).

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[182] Charisiadis, P., S.S. Andra, K.C. Makris, M. Christoudoulou, C.A. Christophi, S. Kargaki, E.G. Stephanou. (2014). Household cleaning activities as noningestion exposure determinants of urinary trihalomethanes. *Environmental Science Technology*. 48(1):770-80.

[183] Lee, J., E.S. Kim, B.S. Roh, S.W. Eom, K.D. Zoh. (2013). Occurrence of disinfection byproducts in tap water distribution systems and their associated health risk. *Environmental Monitoring Assessment*. 2013 Sep;185(9):7675-91

[184] Rahman, M. B., Cowie, C., Driscoll, T., Summerhayes, R. J., Armstrong, B. K., & Clements, M. S. (2014). Colon and rectal cancer incidence and water trihalomethane concentrations in New South Wales, Australia. *BMC Cancer*, 14:445.

Using chlorine dioxide does not result in the formation of chlorinated or brominated disinfection byproducts, such as THMs or HAAs. Chlorine dioxide is not a chlorinating agent and can be used as a primary disinfectant or as a raw water oxidant for THM and HAA precursor reduction in potable water treatment systems—in fact, an increasing number of public water systems in the U.S. now use chlorine dioxide as the disinfectant, over chlorine or chloramine materials, because it doesn't produce THMs or HAAs and yet is highly effective. Chlorine dioxide does produce other DBPs, mainly the inorganic derivatives of chlorite and chlorate, which all have negative health impacts as well. Newer research shows increased levels of congenital anomalies in newborns if the mothers have been exposed to high levels of both chlorite and chlorate.[185]

Alternatives exist

The NOSB should be looking at non-chlorine alternative disinfectants (other than the residual level in finished drinking water). Alternative materials that could potentially be substituted for chlorine materials include citric acid, hydrogen peroxide, l-lactic acid, ethanol, isopropanol, peracetic acid, copper sulfate, and ozone. Alternative practices include steam sterilization and UV radiation.

EPA's Design for the Environment (DfE) program has been investigating alternative disinfectants. A DfE label on a disinfectant means that the product meets the following criteria:

- It is in the least-hazardous classes (i.e., III and IV) of EPA's acute toxicity category hierarchy;
- It is unlikely to have carcinogenic or endocrine disruptor properties;
- It is unlikely to cause developmental, reproductive, mutagenic, or neurotoxicity issues;
- It has no outstanding "conditional registration" data issues;
- EPA has reviewed and accepted mixtures, including inert ingredients;
- It does not require the use of Agency-mandated personal protective equipment;
- It has no unresolved or unreasonable adverse effects reported;
- It has no unresolved efficacy failures (associated with the Antimicrobial Testing Program or otherwise);
- It has no unresolved compliance or enforcement actions associated with it; and
- It has the identical formulation as the one identified in the DfE application reviewed by EPA.[186]

The EPA has approved the following for use as DfE disinfectant products: citric acid, hydrogen peroxide, l-lactic acid, ethanol, and isopropanol. DfE disinfectant product

[185] Righi, E., Bechtold, P., Mariosa, D., Mastroianni, K., Giacobazzi, P., Predieri, G., Aggazzotti, G. (2011). Chlorate and Chlorite Exposure via Drinking Water During Pregnancy and the Risk of Congenital Anomalies. *Epidemiology*, *22*:S125-S125.

[186] http://www.epa.gov/pesticides/regulating/labels/design-dfe-pilot.html

formulations and "inert" ingredients must also meet the DfE standard for safer cleaning products.[187] **All of the approved DfE disinfectant active ingredients are on the National List.** Citric and lactic acids are considered non-synthetic, are listed under §205.605(a), and do not need to be listed in order to be used in crop or livestock production. In addition, the need for clean equipment must be distinguished from the need for disinfection, and disinfection is difficult to accomplish if a surface is not clean.[188]

Technical Reviews on chlorine have identified the following alternative materials: ethanol and isopropanol; copper sulfate; peracetic acid, for use in disinfecting equipment, seed, and asexually propagated planting material; soap-based algaecide/demossers; phosphoric acid; and ozone. The TRs also identified two alternative practices: steam sterilization and UV radiation.[189]

Results of Cornucopia's Certified Organic Livestock Producer Survey

In our latest survey of certified organic livestock producers, out of 28 respondents 39% said they used sodium hypochlorite on occasion to disinfect equipment, and just one producer said they utilized chlorine dioxide. **Not one producer mentioned using calcium hypochlorite.**

Of concern is whether or not certain livestock producers, namely dairy farmers, are required to use chlorine-based disinfectants in order to meet their milk buyers' requirements or state or federal laws (such as the FDA's pasteurized milk ordinance). Four producers out of 28 (14.3%) mentioned that they were required to use bleach to disinfect their milking equipment. In at least one case, state regulators specified they keep Clorox brand bleach in the milk house at all times.

Alternatives used by survey respondents include 2 using peracetic acid, 1 using hot water pressure washing, and 1 using Super San peroxide-based disinfectant.

International regulations

The Canadian General Standards Board permits bleach (not exceeding 10%) for use in packaging and sanitation. Additionally, it is an acceptable agent for cleaning equipment when used in the production and processing of maple syrup.[190]

[187] http://www.epa.gov/dfe/pubs/projects/formulat/dfe_criteria_for_cleaning_products_10_09.pdf
[188] Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008. http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf
[189] 2011 Crops TR and 2006 Livestock TR.
[190] http://www.tpsgc-pwgsc.gc.ca/cgsb/on_the_net/organic/032_0310_1999-e.pdf

The European Economic Community (EEC) Council Regulations 834/2007 and 889/2008 allow sodium hypochlorite (as liquid bleach) for the cleaning and disinfecting of livestock buildings and installations.[191]

Previous subcommittee discussions and vote

On March 7, 2001, the Crops Subcommittee made a recommendation to relist chlorine compounds with a change to the annotation of the following chlorine materials (calcium hypochlorite, chlorine dioxide, and sodium hypochlorite): for pre-harvest use, residual chlorine levels in the water in direct crop contact or as water from cleaning irrigation systems applied to soil must not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act. For disinfecting or sanitizing equipment or tools or in edible sprout production, chlorine products may be used up to maximum labeled rates.

While there were concerns about the relisting of these materials for 2017 Sunset, chlorine has been used for many years as a sanitizer and is necessary in the organic industry for proper sanitation. There are also specific requirements to use chlorine above the 4 ppm SDWA limit in several commodity specific industries. For example, the Pasteurized Milk Ordinance states that the product-contact surfaces of all multi-use containers, equipment, and utensils used in the handling, storage, or transportation of milk, shall be sanitized before each usage.

Crops Subcommittee motion to remove calcium hypochlorite from §205.601(a)
Yes: 1 No: 4 Abstain: 0 Absent: Recuse: 0

Crops Subcommittee motion to remove chlorine dioxide from §205.601(a)
Yes: 1 No: 4 Abstain: 0 Absent: Recuse: 0

Crops Subcommittee motion to remove sodium hypochlorite from §205.601(a)
Yes: 1 No: 4 Abstain: 0 Absent: Recuse: 0

Handling Subcommittee motion to remove chlorine materials from §205.600(b)
Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

Livestock Subcommittee motion to remove chlorine materials (calcium hypochlorite, sodium hypochlorite, chlorine dioxide) from §205.603(a)
Yes: 0 No: 5 Abstain: 0 Absent: 1 Recuse: 0

CONCLUSION

The Cornucopia Institute **remains neutral in the relisting of chlorine compounds as allowed synthetic substances to §205.601, §205.603, and §205.606.** The subcommittees must take into consideration the widespread environmental impacts and

[191] http://eurlex.europa.eu/LexUriServ/site/en/oj/2007/l_189/l_18920070720en00010023.pdf; http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:250:0001:0084:EN:PDF

threats to human health posed by the manufacture, use, and disposal of chlorine.
Limitations on the use of chlorine should be clarified. We recommend that all three listings for "chlorine materials" be replaced with the following language:

> Chlorine materials, as present as residual chlorine levels in water delivered by municipal or other public water systems, which shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.
> (i) Calcium hypochlorite.
> (ii) Chlorine dioxide.
> (iii) Sodium hypochlorite.

Colors Derived from Agricultural Products – 2017 Sunset

SUMMARY

The Cornucopia Institute **opposes the relisting of colors** under 7 CFR §205.606(d) Colors derived from agricultural products.

Rationale:

- **Colors are commercially available in organic form in sufficient supply**.
- Non-organic colors are derived from agricultural products, grown using chemical intensive agriculture.
- Past recommendations have not taken into account the impacts of chemical-intensive agriculture.
- These pigments are highly concentrated, and most often extracted from parts of fruits or vegetables likely to contain the highest levels of contaminants. Current research is lacking to determine any resulting impact to human health.
- Consumers expect organic food to be unadulterated—that is, without having its essential characteristics manipulated with the addition of non-organic ingredients, whether to enhance colors or flavors.

DISCUSSION

The addition of colors to food products serves various purposes: to enhance appearance and attractiveness of the food, to ensure uniformity of color, to replace color that was lost during processing, to accentuate existing colors, to preserve flavor, and to protect light-sensitive vitamins.

The people who choose to eat organic food do so because organic production is supposed to guarantee that, in addition to producing more healthy food products, it minimizes impacts on farmworkers and the environment, including soil and water resources, wildlife, and beneficial insects. In its August 2010 recommendation for §205.606 Sunset review of Colors Derived from Agricultural Products, the NOSB stated:

> *A review of the original petitions and recommendations, historical documents, and public comments does not reveal unacceptable risks to the environment, human or animal health as a result of the use or manufacture of these colors. There is no new information contradicting the original recommendation which were the basis for the previous NOSB decisions to list these colors. As §205.606 listed materials, all are subject to commercial availability scrutiny for use in organic products*.

In 2010 it had been established for a very long time that chemical-intensive agriculture led to "unacceptable risks to the environment, human or animal health." Indeed, in 1962 Rachel Carson's *Silent Spring* led to the ban of DDT and to the formation of the EPA, which

was created for the purpose of protecting human health and the environment by writing and enforcing regulations based on laws passed by congress.

Since then, the EPA has provided regulatory and enforcement oversight to minimize to some extent the impact of chemical agriculture on environmental and human health. Its efforts have often been hindered by undue influences, be they from large chemical corporations or a hostile Congress or administration.

The ineffectiveness of the EPA at protecting the environment and ensuring a safe supply of food contributed to the advent of the organic food movement in the 1970s, which led to the Organic Food Production Act of 1990 and the creation of the NOP in 2000 for the purpose of guaranteeing a safe supply of food produced with minimal impacts to human and environment health.

Thus, it is ironic that the NOSB Board states that no "unacceptable risks to the environment, human or animal health as a result of the use or manufacture of these colors" were found.

These colors are obtained from conventional agriculture, **a chemical-intensive** approach that uses many pesticides,[192] toxic chemical compounds that negatively impact the greater environment, the farmworkers, the customers due to residues, as well as **poison**, and deplete the soil affecting its ability to produce food over the long-term and threatening the survival of the human species.

[192] http://www.beyondpesticides.org/organicfood/conscience/navigation.php

Table 2. Human and Environmental Health Impact Due to Conventional Production of "Natural Colors"

Color Name	Pigment Type(s) or Name	Human and Environmental Health Impacts of Conventional Production[193]	Sufficient Supply of Organic Alternatives Exist?[194] [195] [196] [197] [198]
Beet juice extract color	betalain	❷	Yes
Beta-carotene extract color	carotenoid	❷	Yes
Black currant juice color	anthocyanin	❷	Yes
Black/purple carrot juice color	anthocyanin, carotenoid	❷	Yes
Blueberry juice color	anthocyanin	❸	Yes
Carrot juice color	carotenoid	❷	Yes
Cherry juice color	anthocyanin	❷	Yes
Chokeberry-Aronia juice color	anthocyanin	❷	Yes
Elderberry juice color	anthocyanin	❷	Likely
Grape juice color	anthocyanin	❸	Yes
Grape skin extract color	anthocyanin	❸	Likely
Paprika color	carotenoid, xanthophyll	❷	Likely
Pumpkin juice color	Lutein	❸	Likely
Purple potato juice color	anthocyanin	❷	Likely
Red cabbage extract color	anthocyanin	❷	Likely
Red radish extract color	anthocyanin	❷	Likely
Saffron extract color	carotenoid	❶	Likely
Turmeric extract color	curcuminoid	❷	Likely

Legend: ❶ = significant / ❷ = very significant / ❸ = acute

In spite of the fact that the use of such compounds is not compatible with a system of sustainable agriculture [§6518 m.7], past recommendations have not taken into account the impacts of chemical-intensive agriculture from which these materials are derived.

Human and environmental health concerns

Fruits and vegetables conventionally grown may contain pesticides, which are limited by pesticide tolerances for food products, regulated by the U.S. EPA.[199] The U.S. FDA routinely monitors for pesticides residues on fruits and vegetables to ensure that food products

[193] http://www.beyondpesticides.org/organicfood/conscience/navigation.php .
[194] http://www.fruitjuiceconcentrate.org/our-products
[195] http://naturesflavors.com/ingredients/juice-concentrates/organic-juice-concentrates
[196] http://www.cascadianfarm.com/products/juice-concentrates
[197] http://www.sunopta.com/fruits/juice-concentrates.aspx
[198] http://www.lakewoodjuices.com/products
[199] Colors – 2015 TR, pp 689-690

(domestic or imported) comply with pesticide tolerance.[200] Whether or not the currently established pesticide tolerances reflect the recent advances in residue analysis instrumentation or provide an adequate protection to the public is left for another discussion.

A source of color is grape skin extract. Close to 50% of the samples tested by the EPA in 2010 showed residues of imidacloprid, an insecticide, and two of these samples exceeded tolerance levels.[201]

The Beyond Pesticides database shows that while grapes grown with toxic chemicals show low pesticide residues on the finished commodity, there are 124 pesticides with established tolerances for grapes, 36 are acutely toxic creating a hazardous environment for farmworkers, 109 are linked to chronic health problems (such as cancer), 20 contaminate streams or groundwater, and 99 are poisonous to wildlife.[202]

The 2007 petition by the manufacturers of the conventionally grown colorants states that "**Because natural colorants are concentrated and very strong, they are used in organic food and beverage products at very low levels…".**[203]

This would imply, for example, that in order to extract color from grape skins, it would take a great many grape skins to produce a small amount of colorant, thus the pesticide residues and definitely the copper residues (copper-based products are extensively used in the wine industry to control fungal diseases) would end up being very concentrated.

It appears the NOSB has never considered the implication of concentrating extracts obtained from plants grown using a chemical-intensive approach. The TR, Compiled by ICF International, mentions the possibility of finding pesticides residues on the fruits and vegetables used as sources of colors, **but does not address the possibility of high pesticide residue levels in concentrated fruit or vegetable extracts,** a logical and fairly straightforward consideration, fully supported by the industry's own admission as to the concentration of natural colorants!

A full web search, including a Google Scholar search, did not find anything related to that topic. Is that because nobody has thought about it? It is doubtful. Perhaps it has to do with the technical challenge posed by the analysis of concentrated pigments. This was indicated by the results found on Google Scholar suggesting that natural **pigments interfere with pesticide residue analysis** and need to be separated/removed during the analysis process.[204] Therefore, the high pigment concentration in concentrated juice or vegetable

[200] U.S. EPA. 2014. Pesticide Tolerances. Office of Pesticide Programs, U.S. Environmental Protection Agency. Available: http://www.epa.gov/pesticides/regulating/tolerances.htm
[201] Colors – 2015 TR, pp 704-706
[202] http://www.beyondpesticides.org/organicfood/conscience/index.php?pid=610
[203] Petition for the Addition of Non-Organic Agricultural Substance to the National List Pursuant to Section §205.606. Page 3 – January 15, 2007. http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5057458
[204] http://www.sciencedirect.com/science/article/pii/S0021967303005399

extracts would likely create a significant interference and thus a challenge to the analysis of pesticides residues. Perhaps this is why no one seems to have undertaken such a project, in addition to the fact that the use of "natural" colors is still very limited, but actively growing.[205]

The main point of course is that no one seems to have looked at the potential accumulation and resulting high levels of pesticide residues in concentrated fruit and vegetable extracts and thus it would make sense to error on the side of caution until this possibility is further investigated and allow the colors in §205.606 to sunset.

Essentiality

Is there a need for "**organic enhanced food**"? That is, food with added colors or flavors that have been manipulated with "natural" derivatives of non-organic crops?

Another expectation consumers have is that organic food or its essential characteristics will not be modified with non-organic ingredients (otherwise prohibited) added for non-essential purposes such as enhancing appearance or intensifying flavors**.** If manufacturers feel consumers desire colors added to their organic food they should be derived from colors obtained from organic fruits or vegetables.

Is the current supply of organic fruits and vegetables sufficient to provide the amounts of colorants needed by the industry?

The 2007 National List petition by the manufacturers of conventionally grown natural colorants claimed at the time that the supply was insufficient. However, the organic industry has grown steadily every year over the last seven years,[206, 207] which has likely increased the supply of organic fresh fruits and vegetables. A quick web search found that several of the sources of organic fruit and vegetable extracts used as colors are readily available as juice concentrates.[208],[209],[210],[211],[212] This convincingly demonstrates that organic agriculture can now supply most, if not all, of these substances.

Materials should be removed from §205.606 if they can be supplied organically. And of course, if these materials are allowed to sunset, whether the organic production may or may not be sufficient, the demand will create a supply, a process stimulating growth, benefiting the organic industry and the economy.

[205] http://naturesflavors.com/baking/organic-baking/organic-food-colors
[206] http://www.ers.usda.gov/data-products/chart-gallery/detail.aspx?chartId=35003
[207] https://www.ota.com/what-ota-does/market-analysis
[208] http://www.fruitjuiceconcentrate.org/our-products
[209] http://naturesflavors.com/ingredients/juice-concentrates/organic-juice-concentrates
[210] http://www.cascadianfarm.com/products/juice-concentrates
[211] http://www.sunopta.com/fruits/juice-concentrates.aspx
[212] http://www.lakewoodjuices.com/products

Handling Subcommittee deliberation and vote

The availability of colors in organic form was discussed and based on the public comments made during the spring 2015 NOSB meeting and the HS present understanding that, except for four (4) colors (Beet Juice extract color, Blackcurrant Juice color, Pumpkin Juice color and Red Cabbage extract color) that may not presently be commercially available in organic form, the Handling Subcommittee recommends removing from the National List the following 13 colors: Black/Purple Carrot Juice color; Blueberry Juice color; Carrot Juice color; Cherry Juice color; Chokeberry/Aronia Juice color; Elderberry Juice color; Grape Juice color; Grape Skin Extract color; Purple Potato juice color; Red radish Extract color; Saffron Extract color; Turmeric Extract color; Paprika color.

While we applaud the handling subcommittee recommendations, we strongly urge the NOSB, based on the fact that organic forms of these colors are available commercially and on the other arguments and evidences provided in this review, to consider the removal of all colors from §205.606.

Vote in Subcommittee Motion to remove the four (4) colors as listed above from 205.606
Motion by: Jean Richardson
Seconded by: Zea Sonnabend
Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0

Vote in Subcommittee Motion to remove the thirteen (13) colors as listed above from 205.606
Motion by: Jean Richardson
Seconded by: Lisa de Lima
Yes: 7 No: 0 Abstain: 0 Absent: 0 Recuse: 0

CONCLUSION

The Cornucopia Institute **rejects** the relisting of **colors** on the National List under §205.606 Non-organically produced agricultural products allowed as ingredients in or on processed products labeled as "organic."

Colors from non-organic fruit or vegetable sources **may contain significant amount of pesticide residues**, a human health threat. In addition, there appears to be **a sufficient supply of organic sources of fruit and vegetable extracts** used as colors to justify the removal of all colors from §205.606(d).

Fish Oil – 2017 Sunset

SUMMARY

The Cornucopia Institute **opposes the relisting of fish oil** on the National List under §205.606 as a non-organically produced ingredient allowed in or on processed products labeled as "organic" **without rigorous annotations related to environmental and human health concerns.** Currently fish oil is not sourced sustainably, the benefit to human health is controversial, and the addition of fish oil to any product is non-essential.

If fish oil is relisted under §205.606, The Cornucopia Institute recommends the addition of an annotation requiring users to document that the fish is sourced from sustainable fisheries regulated to prevent overfishing. Furthermore, The Cornucopia Institute recommends that the Handling Subcommittee investigate the necessity of adding fish oil to products labeled as "organic" when alternative sources of fatty acids may exist that are certified organic and/or obtained from a more sustainable source. The Handling Subcommittee should utilize the gathered data to propose an annotation for specific uses allowed for fish oil.

Rationale:

- **Alternative whole foods** exist, such as whole fish, which provide the same or similar benefits as those attributed to fish oil, calling into question whether or not fish oil is a necessary additive to organic food.
- There are certified organic sources for omega-3 fatty acids, including flax seed and chia seed oils.
- There is no definitive medical evidence that fish oils are an inherently superior source of fatty acids, as compared to other fatty acid sources. Studies have shown mixed human health results with fish oil as a supplement, and research is ongoing and controversial.
- The production of fish oil requires the harvest of wild-caught fish, which places a burden on world fisheries, threatened species, and sensitive marine ecosystems.
- There is an increased risk of heavy metal and toxic chemical exposure associated with the consumption of fish oils.
- The addition of fish oil, as a nutraceutical, is not essential to the manufacture of any of the organic foods it is currently being added to. Prohibiting this material for use in organic food still allows consumers the option of purchasing supplements if they deem them efficacious.

DISCUSSION

Fish oil has been allowed as an additive in food labeled as organic with the annotation that it is stabilized with organic ingredients or with ingredients on the National List.[213] Fish oil

[213] 7 CFR §205.606(f).

is touted as an important additive to human diets for its high concentration of omega-3 fatty acids, in particular **EPA** (eicosapentaenoic acid) and **DHA** (docosahexaenoic acid). There are plant sources for omega-3s, including walnuts, flaxseed, and leafy vegetables. Several studies indicate that obtaining beneficial fatty acids from whole foods is more advantageous than supplements due to rancidity and increases in heavy metal content.[214,215,216]

Fish oil is not commercially available in organic form because there is no source of certified organic fish. Fish oil, by necessity, **is obtained from fish harvested from wild stock**. Farmed fish do not have the same oil profile or content without specifically formulated diets. In fact, farmed fish are given fish oil derived from wild stock to ensure that the finished farmed product has nutritive benefits similar to wild fish.[217,218]

An exemption for a prohibited substance in organic production and handling operations should be allowed only if:

- It is not harmful to human health or the environment;
- It is necessary to the production or handling of the agricultural product, because of the unavailability of wholly natural substitutes; and
- It is consistent with organic farming and handling.[219]

Fish oil does not meet these requirements. In particular, there are serious issues of sustainability that are not compatible with OFPA, and fish oil supplementation is not necessary to any organic product.

It is crucial that sustainability requirements are established for organic labeled foods with added fish oil.

Technical Report

The 2015 TR is incomplete. It does not include any in-depth review about the issues of sustainability that arise when fish products are used. Specifically, the report does not discuss the potentially irreversible damages to marine ecosystems that may result from overfishing. These issues need to be addressed whenever fish products are used under the "organic" label.

The 2015 TR does not review or discuss the **essentiality** of fish oil, in particular why fish oil might be **necessary** as an additive in products labeled "organic." The fact that fish oil is used as a functional food ingredient, as well as a nutritional supplement to increase the

[214] http://www.ncbi.nlm.nih.gov/pubmed/25072735
[215] http://jama.jamanetwork.com/article.aspx?articleid=195543
[216] http://www.ncbi.nlm.nih.gov/pubmed/26400434
[217] NOAA/NMFS. Feeds For Aquaculture. http://www.nmfs.noaa.gov/aquaculture/faqs/faq_feeds.html#1what
[218] A significant percentage of the fish oil produced worldwide is used to feed farmed fish – usually farmed salmon. FAO: World Review of Fisheries and Aquaculture 2008: Highlights of Special Studies, Rome. Available at: ftp://ftp.fao.org/docrep/fao/011/i0250e/i0250e03.pdf
[219] 7 U.S.C. 6517(c)(1) National List – Guidelines for prohibitions or exemptions

amount of omega-3 fatty acids in the diet, does not explain why alternative sources of beneficial organically derived fatty acids could not be utilized instead.

Potential human health considerations associated with fish oil ingestion were not fully explored in the report. There is evidence that fish oils being sold for human consumption may not contain the levels of fatty acids that producers claim, may be rancid, and may contain toxins detrimental to human health.[220,221] It would be advisable for a technical report to review and discuss these considerations in depth.

The effects of fish oil on human health

Omega-3s are most studied in regard to their association with cardiovascular disease, and fish-based sources of omega-3s are positively associated with heart health.[222] Supplementation with fats found in fish oil has been found to reduce the risk of sudden cardiac death and to decrease repeat heart attacks.[223] Much of the available research appears to review the effect of EPA and DHA supplementation in people who already have some indicators of cardiovascular disease.[224] However, recent studies show that nut and olive oils are also associated with increased cardiovascular health, and that the consumption of seafood fats may not be as beneficial as previously believed.[225] In addition, consumption of too many omega-3s is associated with a risk of bleeding and stroke.[226] This may be a concern when a multitude of products are supplemented with fish oil, so that people cannot easily track their omega-3 intake.

With respect to the consumption of fish oil during pregnancy and following birth, health advocates for fish oil claim that supplementation helps babies' brains and eyes develop. However, studies supporting these claims contain flaws that suggest further research is needed.[227] A large study published in 2010 concluded that DHA supplementation (with

[220] http://www.ncbi.nlm.nih.gov/pubmed/25072735
[221] http://www.ncbi.nlm.nih.gov/pubmed/26400434
[222] Rizos EC, Ntzani EE, Bika E, Kostapanos MS, Elisaf MS (September 2012). "Association Between Omega-3 Fatty Acid Supplementation and Risk of Major Cardiovascular Disease Events A Systematic Review and Meta-analysis". JAMA 308 (10): 1024–1033. PMID 22968891, available at https://www.ncbi.nlm.nih.gov/pubmed/22968891
[223] *Omega-3 Fatty Acids: An Essential Contribution*. The Nutrition Source. Harvard T.H. Chan School of Public Health. Retrieved September 23, 2015. *Available at:* http://www.hsph.harvard.edu/nutritionsource/omega-3-fats/
[224] S*ee* American Heart Association. *Fish and Omega-3 Fatty Acids. Available at:* http://www.heart.org/HEARTORG/GettingHealthy/NutritionCenter/HealthyDietGoals/Fish-and-Omega-3-Fatty-Acids_UCM_303248_Article.jsp
[225] *Dietary fats and cardiovascular disease: Putting together the pieces of a complicated puzzle*; George Michas, Renata Micha, Antonis Zampelas. Atherosclerosis: Volume 234, Issue 2, June 2014, Pages 320–328. http://www.sciencedirect.com/science/article/pii/S0021915014001622
[226] University of Maryland Medical Center. *Guide to supplements: Omega-3 fatty acids*. Last accessed September 23, 2015. Available at: http://umm.edu/health/medical/altmed/supplement/omega3-fatty-acids
[227] *Fish Oil Use in Pregnancy Didn't Make Babies Smart*, Pam Belluck. OCT. 19, 2010. New York Times (Online). Last accessed September 23, 2015. Available at: http://www.nytimes.com/2010/10/20/health/research/20fishoil.html?_r=0

fish-oil capsules) did not result in improved brain development in young children.[228] In fact, the FDA advises pregnant women to eat whole fish, avoiding the fish that accumulate heavy metals, rather than to take supplements.[229]

Consumption of fish oil may pose some direct dangers to human health. Fatty predatory fish harvested for their oils may have accumulated significant amounts of toxic substances in their tissues due to their position at the top of the food chain.[230] These toxic contaminants, such as mercury in the form of methylmercury[231], polychlorinated dioxins, and PCBs (and many others), are generally fat-soluble and may be present in fish oil. For this reason, the Environmental Protection Agency recommends limiting consumption of certain fish species due to high levels of toxic contaminants that may likely be found in their flesh.[232,233]

Quality problems have been identified in independent tests of marketed supplements containing fish oil. These problems include contamination, inaccurate listing of EPA and DHA levels, spoilage, and formulation issues.[234] It is unclear how much these inconsistencies would affect the quality or integrity of the fish oil used as an additive in products falling under the "organic" label, as these products have not been tested for these concerns yet. Additional investigation should be done on this issue.

Another human health consideration is the abuse of workers. **Fish oil can be derived from forage fish that are harvested using practices that disregard basic human rights.** In some cases, the people who harvest these fish are forced to work as slaves, as reported by the *New York Times*.[235] Potential harmful exploitive practices include human trafficking, physical abuse, starvation, and even death. **Tracking the origin of the fish product to ensure it is harvested in a manner that prevents human suffering is needed to preserve the integrity of organics.**

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[228] Maria Makrides, BSc, BND, PhD; Robert A. Gibson, BSc, PhD; Andrew J. McPhee, MBBS; Lisa Yelland, BSc; Julie Quinlivan, MBBS, PhD; Philip Ryan, MBBS, BSc; and the DOMInO Investigative Team. Effect of DHA Supplementation During Pregnancy on Maternal Depression and Neurodevelopment of Young ChildrenA Randomized Controlled Trial. JAMA: Journal of the American Medical Association. October 20, 2010, Vol 304, No. 15. Available at: http://jama.jamanetwork.com/article.aspx?articleid=186750

[229] http://www.ncbi.nlm.nih.gov/pubmed/25072735

[230] Suedel, B.C., Boraczek, J.A., Peddicord, R.K., Clifford, P.A. and Dillon, T.M., 1994. Trophic transfer and biomagnification potential of contaminants in aquatic ecosystems. Reviews of Environmental Contamination and Toxicology 136: 21–89. *Available at:* http://www.ncbi.nlm.nih.gov/pubmed/8029491

[231] United States Environmental Protection Agency (December 1997). *Mercury Study Report to Congress* (PDF) 3. Washington, D.C.: United States Environmental Protection Agency.

[232] EPA (Last updated on 12/29/2014). Fish Consumption Advice. http://www.epa.gov/mercury/advisories.htm Retrieved September 22, 2015.

[233] EPA Fish Consumption Advisories. Last accessed September 23, 2015. A*vailable at*: http://water.epa.gov/scitech/swguidance/fishshellfish/fishadvisories/index.cfm

[234] Consumer Lab Reviews of Fish Oil Supplements. Last Accessed September 23, 2015. https://www.consumerlab.com/reviews/fish_oil_supplements_review/omega3/

[235] 'Sea Slaves': The Human Misery That Feeds Pets and Livestock, by Ian Urbina, July 27, 2015. New York Times. Last accessed September 23, 2015. Available at: http://www.nytimes.com/2015/07/27/world/outlaw-ocean-thailand-fishing-sea-slaves-pets.html?_r=0

Altogether, supplementation with fish oil gives few definitive benefits to the population at large. Instead, research shows that supplementation of both EPA and DHA seems to have a positive effect on human health in **specific circumstances** (such as active cardiovascular disease). In addition, prohibiting the use of fish oil supplement in organic food still allows consumers the option of purchasing fish oil supplements if they deem them efficacious.

Environmental concerns

Environmental sustainability is a primary concern associated with fish oil use and consumption. The negative effects of overfishing on our oceans are multifaceted and were not fully explored in the 2015 TR.

Small species considered low on the food chain (such as menhaden, sardines, and anchovies) are the types most frequently harvested for fish oil production. Harvesting too many small oily fish has a detrimental effect on the whole food web: predators of the small fish decrease (including the large fish preferred by humans and marine mammals), and prey species that compete with the small fish proliferate and cause further environmental imbalance.[236] For example, the harvest of menhaden for fish oil in the Atlantic has devastated the local marine environment and led to a proliferation of algae (which the fish normally eat), muddying the waters and leading to "dead zones."[237]

Developing sustainable fisheries is an ongoing worldwide struggle. Most of the major fisheries are in decline or in critical condition.[238] The current regulatory model for sustainable fisheries may be too lax when compared to scientific recommendations.

Aquaculture is not a solution to overfishing in respect to fish oil consumption because, as already discussed, farmed fish are fed fish oils. Recent data cited by the National Oceanic and Atmospheric Administration (NOAA)[239] indicates that production of one pound of farmed salmon uses the fish oil from about five pounds of wild fish.[240]
A blanket approval of all types of fish oil will not take into account these serious sustainability concerns. To preserve the integrity of the organic label, additional review and more in-depth discussion of these issues is needed. Every two years the Food and Agricultural Organization of the United Nations publishes a report on the state of world fisheries and aquaculture that should be helpful for further discussion and review of fish

[236] Shannon, L., Coll, M., Neira, S., & Cary, P. (2009). Impacts of fishing and climate change explored using trophic models. *Climate change and small pelagic fish*, 158. *Available at:* http://www.cmima.csic.es/files/webcmima/docs/biblio-pdf/doc_2475.pdf

[237] A Fish Oil Story, by Paul Greenburg. New York Times, Dec. 15, 2009. http://www.nytimes.com/2009/12/16/opinion/16greenberg.html

[238] Hilborn, Ray. *"Are Sustainable Fisheries Achievable?"* Chapter 15, pp. 247–259, in Norse and Crowder (2005).

[239] The National Oceanic and Atmospheric Administration, website available at http://www.noaa.gov/

[240] NOAA/NMFS. Feeds for Aquaculture (item 17). Last accessed September 23, 2015. Available at: http://www.nmfs.noaa.gov/aquaculture/faqs/faq_feeds.html#14are

oil's status.[241] In the meantime, The Cornucopia Institute recommends that if fish oil is relisted, an annotation be added, **requiring that fish oil be sourced from healthy fisheries regulated to prevent overfishing based on scientific recommendations.**

Handling Subcommittee action

The Handling Subcommittee identified several concerns regarding the human health and environmental impact of fish oil. In addition, the subcommittee identified several questions relating to the continued listing of fish oil.

The subcommittee motioned to remove fish oil from the National List based on the following criteria in the Organic Foods Production Act and/or §205.600(b) if applicable: the effect of the substance on human health, environmental conservation, its compatibility with a system of sustainable agriculture and alternative availability of a wholly natural substitute. The vote was: Yes: 2 No: 4 Abstain: 0 Absent: 1 Recuse: 0

CONCLUSION

The Cornucopia Institute **opposes the relisting of fish oil** on the National List without rigorous annotations restricting its use by **requiring that fish oil be sustainably sourced to prevent the environmental collapse of world fisheries and sourcing from specific varieties that have been proven to be low in heavy metals and other contaminants.**

Consumers buy products labeled as "organic" with the presumption that those products are more beneficial to their health and the environment, as compared to conventional products. There are serious concerns associated with the harvest and use of fish oil, making it a suspect candidate for continued inclusion on the National List.

[241] *The State of World Fisheries and Aquaculture.* Rome, 2014. Food and Agriculture Organization of the United Nations. http://www.fao.org/3/a-i3720e.pdf

Glycerides (mono and di) – 2017 Sunset

SUMMARY

The Cornucopia Institute **opposes the relisting of glycerides (mono and di)** under 7 CFR §205.605(b) for use only in drum drying of food.

Rationale:

- Mono- and diglycerides are emulsifiers and are often, but not always, made from hydrogenated oils.
- Mono- and diglycerides produced from hydrogenated fats contain measurable amounts of trans fats.
- The oil refining process generates trans fats, which implies that mono- and diglycerides produced from non-hydrogenated refined oils contain trans fats.
- The consumption of trans fats is linked to increased risk of coronary disease, oxidative stress, inflammation, and possible type-2 diabetes.
- The main sources of mono- and diglycerides are conventionally grown oils. In reviewing the impact of their manufacture, the NOSB must consider the consequences of raising the non-organic crops used to produce it.
- Many oils used in the manufacturing of mono- and diglycerides are often obtained from GMO crops.
- There are alternatives substances, listed on the National list, that are suitable for drum drying of food.
- There are a number of alternative methods and machinery available for drying food products.

DISCUSSION

Glycerides, (mono and di) are listed on the National List at §205.605 as nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))." (b) Synthetics allowed with an annotation specifying for use only in drum drying of food.

Mono- and diglycerides, together with triglycerides, the major constituents of food fats, occur naturally in food as minor constituents of fats.[242] However, these substances are extensively used in the food industry as emulsifiers and as such are produced on an industrial scale. Mono- and diglycerides and their derivatives accounted in 2004 for about 70% of the world production of food emulsifiers and are considered the most important group of emulsifiers.[243] They are manufactured either from animal fats or from vegetable oils such as soybean, canola, sunflower, cottonseed, coconut, or palm oil.[244]

[242] Limited Scope TR - Glycerides (mono and di). Page 2, line 56-57

[243] Whitehurst, R.J., 2004. *Emulsifiers in Food Technology*. Chapter 2, p 40. Blackwell Publishing Ltd.

[244] Frank, Jill. *Prospector: Mono and Diglycerides in Food Products.* May 16, 2014. http://knowledge.ulprospector.com/511/mono-diglycerides-2/

The 2015 Limited Scope TR, compiled by OMRI, is deficient in not mentioning the possibility that trans fats may be used in the manufacture of mono- and diglycerides. However, these substances are often, but not always, made from hydrogenated fats, according to the Environmental Working Group (EWG).[245] Therefore, emulsifiers manufactured with hydrogenated fats, "contain measurable concentrations of trans unsaturated fatty acids," as stated in a textbook for food scientists.[246]

Another fact not addressed by the 2015 TR is that all refined edible oils, such as the oils used in the manufacture of mono- and diglycerides, contain some amount of trans fat as an unintentional byproduct of their manufacturing process.[247]

Generally, the food to be dried is mixed with 0.1% to 1% of these substances. Perhaps that appears to be low; however, according to the Institute of Medicine, trans fats have "no known health benefits" and there is no safe level of ingestion.[248]

In most cases, the products' trans fat content on the nutrition label doesn't add up. The reason: a loophole in federal food labeling regulations allows food processors to round off less than half a gram of trans fat per serving to zero. However, the FDA labeling regulations on trans fats apply only to triglycerides, and not to emulsifiers like mono- and diglycerides.[249] This means that food **labeled as possessing "0% trans fat" will nevertheless contain trans fats from mono- and diglycerides**. In organic food, the allowed use for mono- and diglycerides is as a processing aid and thus may not be labeled as processing aids are not required to be listed on food labels.[250,251]

Children are perhaps most at risk from the half-gram labeling loophole. A recent study found that 80% of children under age 11 exceed recommended trans fat limits.[252] According to the World Health Organization's recommendations,[253] a two-year-old with calorie needs of 1,000 calories should consume no more than 10 calories from trans fat, or less than 1.1 grams a day. For example, food with 0.49 gram of trans fat per serving would make up nearly 50% of a child's daily limit. Two servings of potato chips containing partially hydrogenated oil claiming "0 grams of trans fat" plus the trans fat contributed by mono- and diglycerides could easily exceed a child's recommended limits.

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[245] http://www.ewg.org/research/hidden-plain-sight/trans-fats-hidden-many-foods

[246] Hasenhuettl GL and Hartel RW. 2008. *Food Emulsifiers and Their Applications*, 2nd edition. Springer.

[247] FDA (Food and Drug Administration). 2013a. Tentative Determination Regarding Partially Hydrogenated Oils; Request for Comments and for Scientific Data and Information. Fed. Reg. Vol 78, No. 217: 67169 - 67175, November 8, 2013. Available: https://federalregister.gov/a/2013-26854

[248] National Academies of Science, Institute of Medicine Report: Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids (Macronutrients). 2005.

[249] http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm2006828.htm

[250] http://www.foodinsight.org/Questions_and_Anwers_about_Processing_Aids_Used_in_Modern_Food_Production

[251] http://www.foodsafetynews.com/2013/06/processing-aids-whats-not-on-the-label-and-why/#.VeC-ofZVhuA

[252] Kris-Etherton PM1, Lefevre M, Mensink RP, Petersen B, Fleming J, Flickinger BD. 2012. Trans fatty acid intakes and food sources in the U.S. population: NHANES 1999-2002. Lipids. 47(10): 931-40.

[253] http://www.who.int/dietphysicalactivity/publications/trs916/download/en/

Alternatives and essentiality

There are several substances suitable for drum drying of foods that could be used instead of mono- and diglycerides. These are soy lecithin and gum Arabic (both available in organic forms) as well as a new commercial product with great potential as an alternative emulsifier and drum release agent, **a certified organic rice bran extract called Nu-Rice**.[254,255]

In addition, a number of **different methods and technologies are available for drying food products**, including spray drying, freeze drying, infrared drying, fluidized bed dryers, air lift dryers, scraped wall heat exchangers, and a newer alternative to the traditional thin-film drying methods that, in trials, showed much faster drying times and a higher quality end product as compared to the traditional thin-film drying.[256]

Therefore, when considering the fact that suitable alternative substances and technologies exist for the drum drying of food, it is obvious that **mono- and diglycerides are not essential**. In addition, the potential health issues associated with trans fats combined with the fact that mono- and diglycerides are almost ubiquitous in conventional processed foods warrants the removal of mono- and diglycerides from the National List.

Other considerations

Many of the oils used in the manufacturing of mono- and diglycerides are **often obtained from GMO crops**, including canola, soy, corn, and cottonseed. When reviewing these materials, the NOSB must consider whether their manufacturing base was obtained from excluded methods.

The main sources of mono- and diglycerides are conventionally grown oils. In reviewing the impact of their manufacture, the NOSB must consider the consequences of raising the non-organic crops used to produce these oils.

Finally, the NOSB should take into consideration that the use of mono- and diglycerides in organic food processing is prohibited by the **CODEX Alimentarius Commission, EEC Regulations, Japan Agricultural Standards for Organic Productions, and IFOAM**.[257]

Handling Subcommittee discussion

The history of the inclusion of mono- and diglycerides on the National List was reviewed. The alternatives to drum drying were discussed and the fact that **organic soy lecithin and gum Arabic are alternative substances**.

Further, it was mentioned that the 2015 TR does not identify unacceptable human health or environmental risks. It was also noted that public comments during the Spring 2015

[254] Limited Scope TR - Glycerides (mono and di). Page 11, line 508-551
[255] http://www.ribus.com/nu-rice
[256] Limited Scope TR - Glycerides (mono and di). Page 10-11, line 483-502
[257] Ibid. Page 5, line 204-227

NOSB meeting yielded little additional information and that there was no opposition to the continued listing of mono- and diglycerides.

Vote to remove from National List:

Motion by: Jean Richardson
Seconded by: Harold Austin
Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0

CONCLUSION

The Cornucopia Institute **opposes the relisting of glycerides (mono and di)** under **§205.605(b)** synthetics allowed, given that **alternatives exist** and that the 2015 **Limited Scope TR was inadequately researched and failed to point out that mono- and diglycerides are likely to contain trans fats**, which have no known health benefits and for which there is no safe consumption level.[258] Indeed, trans fats have been associated with increased risks of numerous diseases, including heart disease, stroke, and diabetes. They promote inflammation and obesity, raise bad cholesterol levels, and lower good cholesterol levels.[259, 260]

[258] National Academies of Science, Institute of Medicine Report: Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids (Macronutrients). 2005.
[259] http://www.livestrong.com/article/445850-what-is-bad-about-mono-diglycerides/
[260] University of Maryland Medical Center; "Trans Fats 101"; November 2010

Lactic Acid – 2017 Sunset

SUMMARY

The Cornucopia Institute **supports the listing** of the 2017 sunset material **lactic acid** under §205.605(b) Synthetics allowed, **and opposes the relisting** of **lactic acid** under §205.605(a) Non-synthetics allowed. Even though lactic acid is a natural product, the commercial production process involves a natural process (fermentation) followed by **synthetic chemical reactions, making it a synthetic compound**.

Rationale:

- Even though lactic acid is a naturally occurring compound produced by microbial fermentation, several phases of the commercial production involve synthetic chemical reactions, making it a synthetic substance.[261]
- Lactic acid **should be reclassified as a synthetic** and relisted under §205.605(b) Synthetics allowed.
- Some of the agricultural **feedstock fermented may be from GMO sources**. Annotations prohibiting the use of GMO-derived fermentation feedstock are necessary.
- **Many of this material's uses are prohibited by §205.600(b)(4)** (e.g., as a preservative, for flavor and color enhancement, and for the creation of texture); therefore, if lactic acid were reclassified as a synthetic, those prohibitions would apply to it as well.

DISCUSSION

Lactic acid is a naturally occurring acid that is produced by mammals and other animals, plants, and microorganisms. It occurs naturally in many food products and has been used for centuries to preserve various food products, such as fermented vegetables (e.g., sauerkraut and kimchi), fruits, and meats.

It is widely used in almost every segment of the food industry as an acidulant, a preservative, a stabilizer, a humectant, and as a taste and flavor enhancer.[262]

The NOSB reviewed and recommended lactic acid for listing on the National List in 1995. It is currently listed under §205.605(a) Acids (Alginic; citric – produced by microbial fermentation of carbohydrate substances; and Lactic). It is used in organic food processing for various purposes, as an anti-microbial agent, a curing and pickling agent, a flavoring agent, and to control the pH of various food products.[263]

Lactic acid is commercially produced by the fermentation of agricultural raw materials, such as dextrose (from corn), sucrose (from sugarcane or sugar beets), and starch (from

[261] 2015 TR – Lactic acid and lactates. Page 3, lines 100-112
[262] Ibid. Page 4, lines 137-164
[263] Ibid. Page 5, lines 196-200

barley, corn, malt, potato, rice, tapioca, or wheat). Fermentation processes such as these are considered naturally occurring biological processes. However, calcium carbonate, sulfuric acid, and activated carbon are used to produce the food-grade product during the fermentation and purification phases to convert lactic acid to calcium lactate and then back to lactic acid (synthetic chemical processes). Thus, lactic acid is chemically changed during the production process, even though the original compound is eventually obtained.[264]

Therefore, despite the fact that fermentation is a biological process, the additional reactions necessary during the commercial production process imply a classification of lactic acid as synthetic.

In addition, some of the feedstock used as a source of raw fermentation materials may likely be **GMO (corn, beet, potato)**. As per NOP standards under §205.301(c), such possibility must be addressed by the NOSB when considering its sunset evaluation, and an annotation prohibiting the use of feedstock obtained from excluded methods submitted as a separate proposal is advised.

Human and environmental health concerns

Lactic acid and its salts are GRAS[265] and pose low potential risk to human health. By reducing the risk of foodborne pathogens, the use of lactic acid and its salts in some of the applications can actually be beneficial to human health.[266]

Environmental hazards due to the manufacture or use of lactic acid or its salts are considered low. However, the conventional fermentation-based process creates a surplus of calcium sulfate (gypsum) waste, the disposal of which can be difficult. However, there are some commercial uses for gypsum including the manufacture of plasterboards and as a soil amendment. Other lactic acid production processes are being investigated to enhance efficiency and productivity while diminishing waste production.[267]

Essentiality and alternatives

Commercially produced lactic acid, a synthetic chemical, is widely utilized in the food industry in a variety of ways not easily substituted, as an acidulant, a humectant, a flavor enhancer, and an antimicrobial agent. Lactic acid is often used in place of fermentation (e.g., in cottage cheese production) to avoid risks of failure and contamination.[268]

Lactic acid is currently not produced organically. Other acids listed under §205.605(a), including citric acid, malic acid, and tartaric acid, can be used in place of lactic acid as acidulants and flavor enhancers but may not have the antimicrobial properties as lactic acid.[269,270]

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[264] 2015 TR – Lactic acid and lactates. Page 3, lines 100-112
[265] FDA regulations at 21 CFR 184.1061; 21 CFR 184.1068; 21 CFR 184.1639
[266] 2015 TR – Lactic acid and lactates. Page 17, lines 811-830
[267] Ibid. Page 16-17, lines 770-805
[268] Ibid. Page 17, lines 840-844
[269] 2015 TR – Lactic acid and lactates. Page 17, lines 896-898

Handling Subcommittee discussion and vote

The subcommittee reviewed the history and uses of lactic acid. The subcommittee noted that lactic acid is used in almost every segment of the food industry, that it performs a wide ranges of functions, and that the overwhelming majority of public comments supported its relisting. In actuality, out of 12 comments, 9 were in support and 3 expressed concerns and were neutral as to its relisting.

Vote to remove from the National List:

Motion by: Ashley Swaffar
Seconded by: Tracy Favre
Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0

CONCLUSION

The Cornucopia Institute **opposes** the relisting of lactic acid on the National List under §205.605(a) Non-synthetics allowed, but **supports** the **listing** of lactic acid under §205.605(b) Synthetics allowed.

In so far as the commercial production process necessitates the inclusion of synthetic chemical reactions and that truly non-synthetic lactic acid is unavailable, then lactic acid should be reclassified as synthetic under §205.605(b) and its usage restricted to uses compliant with §205.600(b)(4).

[270] Ibid. Page 18-21, lines 1038-1039

Lecithin, de-oiled – 2017 Sunset

SUMMARY

The Cornucopia Institute **opposes the relisting of lecithin, de-oiled** under 7 CFR §205.606(p). It is used as an emulsifier, surfactant, stabilizer, and preservative in many food products, such as baked goods and chocolates.

Rationale:

- Lecithin, de-oiled is **commercially available in organic form in sufficient supply**.
- The main source of conventional de-oiled lecithin is from soybeans, a chemical-intensive agricultural crop.
- Over 94% of the soybeans grown in the U.S. are **GMO**[271], greatly increasing the chance for non-GMO soybean to be contaminated with GMO soybeans. The Union of Concerned Scientists found **in 2004** that 50% of the conventional non-GMO corn was contaminated with GMO material.[272] How much of the non-GMO soybeans are GMO-contaminated 11 years later?
- Non-organic liquid lecithin is extracted with **hexane**, a dangerous solvent[273], and is de-oiled with acetone another potent and toxic solvent.[274]
- The addition of **various ancillary substances** not approved for organic production in various non-organic de-oiled lecithin formulations is problematic as some of these substances may be derived from GMO crops, or be synthetic and potentially **toxic.**

DISCUSSION

Lecithin has a long and controversial history as a processing ingredient for use in organic food.[275]

Lecithin – unbleached was placed on the original National List apparently without a TAP review. In 1995 lecithin – bleached was added to the National list. During sunset review in April 2006, the Board recognized that there are "plentiful non-synthetic and organic alternatives to synthetic bleached lecithin in liquid form," but at the time there was no such

[271] http://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-us/recent-trends-in-ge-adoption.aspx

[272] http://www.ucsusa.org/sites/default/files/legacy/assets/documents/food_and_agriculture/seedreport_exsum.pdf

[273] U.S. Environmental Protection Agency, Hazard Summary: Hexane (Washington, DC: U.S. EPA, Technology Transfers web site, Air Toxics web site, created April 1992, revised 2000, available online at www.epa.gov/ttn/atw/hlthef/hexane.html).

[274] U.S. Occupational Safety and Hazards Office, Chemical Sampling Information: Acetone (Washington, DC: US Department of Labor, last updated March 2007, available online at http://www.osha.gov/dts/chemicalsampling/data/CH_216600.html).

[275] Behind the Bean – the Social, Environmental, and Health Impacts of Soy. 2009. http://www.cornucopia.org/soysurvey/OrganicSoyReport/behindthebean_color_final.pdf

alternative for "bleached lecithin in dry, de-oiled form." Accordingly, the NOSB originally voted not to relist bleached lecithin in liquid form.

However, in October 2006 the Board felt that it was not possible to renew the dry form and not renew the liquid form of bleached lecithin. Thus, the Board saw no alternative but to recommend renewal of bleached lecithin under 7CFR §205.605(b) Synthetics allowed. In its closing summary, the Board invited a petition to restrict the use of bleached lecithin to dry forms only.

A petition was filed in 2004 to remove lecithin – unbleached from §205.606 and another petition was filed in 2008 to remove lecithin – bleached from §205.605(b). To address the petition, a Technical Report was requested and became available in 2009. This **TR, whose author's identity was withheld from the public by the USDA**, reviewed only bleached lecithin.

At the May 2009 meeting, the NOSB voted to remove the bleached form of lecithin from §205.605(b), because organic forms of lecithin had become available. In a separate vote, the NOSB agreed to remove lecithin – unbleached from §206.606 and to add "lecithin – de-oiled" in §205.606 because in some cases, de-oiled lecithin was the only form appropriate for certain products and **at the time**[276] no organic alternatives were available.

In March 2012, the listing under §205.605(b) for bleached lecithin was removed from the National List, and the listing under §205.606(p) lecithin – unbleached was replaced with (p) lecithin – de-oiled, to clarify which form of lecithin was not available in organic form. This change meant that organic forms of de-oiled lecithin must be used in organic processed products, except when an organic form of de-oiled lecithin is commercially unavailable.

Thus, pertinent to the sunsetting of the listing of non-organic de-oiled lecithin is whether or not organic forms of de-oiled lecithin are available. Indeed, this is part of the additional information requested by NOSB in preparation for the spring 2015 NOSB meeting, considering that the available **2009 TR covers only the bleached form of lecithin and does not address de-oiled lecithin nor its current commercial availability**:

1. ***Has the supply of dry forms of organic unbleached lecithin increased sufficiently since 2009 that this can be removed from the list?***

A web search found several manufacturers and distributors of certified organic de-oiled lecithin in the U.S. and in the world.

Lynn Clarkson, who testified in May 2009 that his company at the time could not make organic de-oiled lecithin, heads Clarkson Soy Products, a company that is now selling and distributing organic de-oiled lecithin.[277]

[276] Lecithin – Organic Evolution. A NOSB presentation by Lynn Clarkson, Clarkson Soy Products. May 5, 2009
[277] http://clarksonsoy.com/organic-lecithins/

When The Cornucopia Institute contacted Curtis Bennett, vice-president of sales for Clarkson Soy Products, Mr. Bennett stated, "The manufacturer of organic de-oiled lecithin has produced this product for over two years, recently opening a second production facility creating a surplus of organic de-oiled lecithin. For the past two years, organic de-oiled lecithin has been sold to small, medium, and large organic companies in the U.S., Canada, Europe, and Australia without any supply issues."

Furthermore, Clarkson Soy Products believes that "*If the NOSB will allow de-oiled lecithin to sunset it is clear that, as dictated by the Law of Supply and Demand, other manufacturers will move ahead with creating more supply*."

This clearly demonstrates that there currently exists several sources and likely a sufficient supply of organic de-oiled lecithin to meet the demand for the processing needs of the organic industry in the U.S.

Thus, the listing of de-oiled lecithin under §205.606 is unnecessary and should be removed.

Handling Subcommittee deliberations and vote

The Handling Subcommittee discussed the public testimonies submitted at the spring 2015 NOSB meeting, mentioning the comment from one supplier as to the availability of organic, de-oiled soy lecithin since 2013. However, comments from the food processing industry seemed to indicate that there were issues as to a dependable supply of organic de-oiled lecithin and consequentially there was a reluctance to rely on just one supplier for this important ingredient. It was also mentioned that there were no comments as to the availability of sunflower or other source lecithin in organic de-oiled forms, an important consideration for soy-free diets. Thus the subcommittee believes that the market has not yet reached the point of having all types of lecithin available in organic form and recommend its renewal on §205.606.

Vote in Subcommittee Motion to remove Lecithin - de-oiled from §205.606
Motion by: Zea Sonnabend
Seconded by: Jean Richardson
Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0

CONCLUSION

The Cornucopia Institute **opposes the relisting of lecithin – de-oiled under §205.606(p)** given the commercial availability of **organic de-oiled lecithin.**

Magnesium Stearate – 2017 Sunset

SUMMARY

The Cornucopia Institute remains **neutral as to the relisting of magnesium stearate** for use as a formulation aid.

Magnesium stearate was added to the National List under §205.605(b) in 1997 as a non-agricultural (non-organic) synthetic substance allowed for use only in agricultural products labeled "made with organic (specified ingredients or food group(s))," prohibited in agricultural products labeled "organic."

It is classified under "Processing Non-agricultural ingredients and Processing Aids" by OMRI and is used as a formulation aid, such as a flowing/binding, anticaking agent and a tablet lubricant in nutritional supplements.

Rationale:

- **The TAP review, dated 1995, is very outdated** and **does not discuss potential alternatives** or new developments in formulation aid.
- The TAP review **does not address environmental issues** associated to sourcing the oils used in the manufacture of stearic acid, magnesium stearate's primary ingredient.
- Magnesium stearate utilization is highly specific as well as limited.
- Magnesium stearate is a substance that is not easily replaced.

DISCUSSION

Magnesium stearate is the magnesium salt of stearic acid. It consists of two molecules of stearic acid combined with a molecule of magnesium, basically a soap, with the same low toxicity associated with this type of compound.[278,279] Soaps are readily metabolized in the soil environment,[280] and due to magnesium stearate's insolubility in water, this substance is not bioavailable and thus poses virtually no threats to aquatic environments.[281]

The Handling Subcommittee notes dated January 27, 2015 state:

> *2017 Sunset (JR) - Magnesium stearate. The document was circulated on Jan. 22. A member noted that it is approved for use in "made with organic" products, and another member indicated that it is really only used in supplements. The group agreed that the more useful questions to ask would be: who is using it and why it is important? HS will add questions to the posting.*

[278] EPA RED 1992

[279] Hera. 2003. Fatty Acid Salts (Soap) Environmental Risk Assessment Draft. Human &Environmental Risk Assessment on ingredients of European household cleaning products. Sept. 2003, 61 pp. found at www.heraproject.com.

[280] EPA RED 1992

[281] EPA EFED 2013: Environmental Fate and Ecological Risk Assessment for the Registration of Soap Salts. http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2008-0519-0019

Undoubtedly, **the use of magnesium stearate in the organic industry is very narrow and highly specific**. It is utilized by the **supplement industry** as a flow agent to aid accurate mixing of multiple ingredients and reduce potential adhesion and flow problems. In addition, its lubricating properties prevent ingredients from sticking to manufacturing equipment during the compression of powder mixtures into solid tablets while its binding properties help these tablets hold together and break apart properly.[282,283] **There are no known effective alternatives that are economically viable at this time**.[284]

Human health concerns

Magnesium stearate is considered a food ingredient by the FDA which recognized it as GRAS in 1976, with upper levels below 2,500 mg/kg per day.[285] For over 40 years it has been used in the manufacture of nutritional and pharmaceutical tablets and capsules.

Magnesium stearate is composed of 6%-8% magnesium (Mg)[286], an essential mineral with an FDA-established daily value of 385 mg, and stearic acid, one of the most common long-chain saturated fatty acids, found in many foods including eggs, chicken, grass-fed beef, coconut oil, walnuts, cheese, chocolate, salmon and human breast milk, among others.[287]

While stearic acid is classified as a saturated fatty acid (SFA), it is unique among the them in that it does not raise plasma cholesterol concentrations, and thus does not increase risk of developing cardiovascular diseases.[288, 289]

Environmental concerns

The main concerns about the utilization of magnesium stearate by the organic supplement industry are specific to the sources of stearic acid, the main ingredient in the manufacture of magnesium stearate.

Stearic acid is commonly **derived from conventional cottonseed, soybean, and canola oils**. **In the U.S., 93% of soy is genetically modified and over 70% of the world soybean crop is genetically modified; 90% of canola grown in the U.S., 94% of cotton grown in the U.S., and 43% of the world cotton crop is genetically modified.**[290, 291]

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[282] http://www.nowfoods.com/Quality/Do-Supplements-Work/M093528.htm
[283] Ibid.
[284] http://www.tabletscapsules.com/Back-Page/Eliminating-magnesium-stearate-from-tablets/?ID=4
[285] FDA's SCOGS Database; Report No. 60; ID Code: 557-04-0; Year: 1979
[286] http://www.nowfoods.com/Quality/Do-Supplements-Work/M093528.htm
[287] http://ndb.nal.usda.gov/ndb/nutrients/index
[288] Kris-Etherton PM, Griel AE, Psota TL, Gebauer SK, Zhang J, Etherton TD. Dietary stearic acid and risk of cardiovascular disease: intake, sources, digestion, and absorption. Lipids. 2005 Dec;40(12):1193-200. Review. View Abstract
[289] Cohn JS, Kamili A, Wat E, Chung RW, Tandy S. Reduction in intestinal cholesterol absorption by various food components: mechanisms and implications. Atheroscler Suppl. 2010 Jun;11(1):45-8. Epub 2010 May 2. Review. View Abstract
[290] http://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-us/recent-trends-in-ge-adoption.aspx

Soybean, cotton, and canola (whether GMO or not) are products of industrial agriculture, an approach to agriculture that significantly impacts farmworkers, animal welfare, water resources, wildlife, and pollinators.[292]

The oils obtained from these crops are rich in oleic acid and linoleic acid, unsaturated oils which are hydrogenated to yield stearic acid.

Hydrogenation is a commercial chemical process by which unsaturated oils are saturated. This saturation reaction is not 100% efficient and some **trans fats are created in the process**. Even though stearic acid is purified after hydrogenation, very minimal contamination by trans fats is possible but realistically insignificant considering the amount (less or equal to1%) of magnesium stearate used per supplement tablet.

To avoid using oils obtained from GMO or pesticide-intensive crops and to sidestep the risk of contamination with trans fats from the processing of these oils, **some manufacturers are using palm oil as a source of stearic acid**.

Mostly produced in Malaysia and Indonesia, palm oil use has risen dramatically in recent years reflecting an increased demand for vegetable oil; currently about a third of all vegetable oil used worldwide is palm oil. This trend is likely to continue as it is the most inexpensive plant-based oil on the market today. There is a large demand for it for biodiesel applications and it is increasingly used as a replacement oil in processed foods because of its low trans fats content.[293]

However, there are significant and **well-documented concerns about the environmental impact of current palm oil production methods**, which often cause the destruction of carbon-rich tropical forest and peatlands and, as such, contribute to global warming.

In addition, oil palm plantations convert the tropical forest habitat into monocultures greatly reducing biodiversity and threatening the populations of endangered species such as the Bornean orangutan and pygmy elephant, and of critically endangered species such as the Sumatran orangutan, tiger, elephant, and countless other forest-dependent species.[294]

Certified Sustainable Palm Oil (CSPO) is now available. This certification is provided by the Roundtable on Sustainable Palm Oil (RSPO), a worldwide body composed of palm oil industry stakeholders and NGOs. However, RSPO certification does not guarantee that forests or peatlands are not destroyed.[295]

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[291] http://www.gmo-compass.org/eng/agri_biotechnology/gmo_planting/342.genetically_modified_soybean_global_area_under_cultivation.html

[292] http://www.ucsusa.org/food_and_agriculture/our-failing-food-system/industrial-agriculture/hidden-costs-of-industrial.html#.VOZk9_nF-So

[293] http://www.ucsusa.org/sites/default/files/legacy/assets/documents/global_warming/palm-oil-and-global-warming.pdf

[294] Ibid.

[295] Ibid.

Alternatively, currently there are a few companies in palm oil-related businesses that exceed RSPO standards to ensure that none of their raw materials contribute to tropical deforestation or peatland depletion.

Lack of adequate review

A very abridged Technical Advisory Panel (TAP) review of magnesium stearate was conducted in 1995 by 2 reviewers only (instead of the usual three). The reviewers were Dr. Joe Montecalvo, a consultant for the organic food processing industry and Dr. Richard Theuer, a former executive and public relation expert at the Beech Nut division of Ralston Purina. **This TAP review provided none of the information necessary to seriously evaluate this compound**. A new and more thorough Technical Review was not requested for this material. A current TR would help estimate any potential additional impacts of its manufacture on the environment. In this case the impacts would be from:

- The chemical intensive agriculture used to produce the oils needed for the manufacture of magnesium stearate;
- The use of GMO crops for oil production; and
- Deforestation and peatland destruction from palm oil production which results in loss of habitat for several critically threatened species and contributes significantly to global warming.

A Technical Review would also help assess whether the organic production of these oils may be sufficient to meet the manufacture demand for the need of magnesium stearate by the organic supplement industry.

Handling Subcommittee discussion and vote

During the second deliberation, on June 16, 2015, it was mentioned that very few to no comments were received in response to the questions requested by the NOSB in advance of the Spring 2015 meeting, about the potential health impacts and alternatives to this material.

This is an inaccurate statement, there were a total of 6 written comments about this material, and three of these comments (50%) addressed these issues.

The notes also mentioned that certifiers provided data on the number of processors using magnesium stearate, a relatively small number. Considering that magnesium stearate is allowed only in agricultural products labeled “made with organic” and is prohibited in agricultural products labeled “organic,” the subcommittee recommended its continued listing.

Vote:

Motion to remove Magnesium stearate from §205.605(b)
Motion by: Jean Richardson
Seconded by: Tracy Favre
Additional Discussion: none
Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0

CONCLUSION

Even though magnesium stearate is a non-toxic substance that appears essential within its very narrow and specific use by the organic supplement industry, it is clear that there are environmental consequences from the production of the oils necessary for its manufacture.

Thus, the evaluation of magnesium stearate must take into consideration the use of pesticides/genetic engineering in the non-organic production of oils used for its manufacture and the availability of organic oils or sustainably produced palm oil for this purpose.

If organic oils or sustainably produced palm oil were to be used in the manufacture of magnesium stearate, it is likely Cornucopia would support its relisting under §205.605(b) without the previous restrictions. Due to its essentiality, highly specific and limited use, The Cornucopia Institute remains **neutral** on this substance until a thorough TR is completed.

Pectin (non-amidated forms only) – 2017 Sunset

SUMMARY

The Cornucopia Institute **supports the relisting of pectin (non-amidated forms only)** under 7 CFR §205.606(s) either as the high-methoxy or low-methoxy form. Pectin is primarily used as a gelling agent and a thickener and stabilizer in jams, jellies, baked goods, dairy products, beverages, sherbets, and margarine, and in non-food applications such as cosmetics and pharmaceuticals.[296]

However, Cornucopia **strongly recommends that the NOSB:**

- **Further investigate the commercial availability of pectin from organic sources as this issue was inadequately addressed in the 2009 TR** and the production of organic fruits and vegetables (from which pectin is extracted) has since significantly increased.
- **Add an annotation** requiring that **only** low-methoxy pectin **obtained via a GMO-free enzymatic process** be allowed as an ingredient in food labeled as organic.
- **Add a second annotation** requiring that pectin formulations may only contain standardizing agents from organic sources and ancillary substances listed on the National List for use in food labeled organic.

Rationale:

- The commercial availability of pectin in organic form has **not** been thoroughly investigated.
- The main source of pectin is from apple pomace and citrus peel, both chemically intensive agricultural crops. In reviewing the impact of the manufacturing of pectin, the NOSB must consider the impacts of raising the non-organic crops used to produce it (and any potential agrichemical residues remaining in the product).
- The 2009 TR for non-amidated low methoxy pectin (LMP) repeatedly states that LMP is most commonly obtained by a chemical process that demethylates high methoxyl pectin (HMP). There are four methods of HMP demethylation: three are chemicals and one is enzymatic. Therefore, it is a synthetic substance and the listing on §205.606 should be limited to high methoxyl pectin (HMP) and to LMP obtained via the enzymatic process.
- **The 2015 Limited Scope TR indicates that several ancillary substances used in pectin formulations are not approved for organic production**.
- Sucrose and dextrose are used interchangeably as standardizing agents in pectin formulations and are likely obtained from GMO crops.

DISCUSSION

Pectin is listed on the National List at §205.606 as a non-organically produced agricultural product allowed as an ingredient in or on processed products labeled as "organic," with an

[296] 2015 Limited Scope TR – Pectin. Page 1, line 15-17

annotation allowing only non-amidated forms. Both high-methoxy and low-methoxy forms are allowed if not commercially available, and as long as they are not amidated.

Pectin is classified as a soluble fiber. It is found in most plants, but is most concentrated in citrus fruits (oranges, lemons, grapefruits) and apples. Pectin is produced commercially by aqueous extraction of citrus peels and apple pomace (both byproducts of the juice industry) or beet pulp under mildly acidic conditions; the extract is filtered and precipitated with alcohol, washed, and dried.

According to the 2009 TR, compiled by the Technical Services Branch for the USDA National Organic Program, pectins are present in many fruits and vegetables in varying amounts and qualities.[297] As such, it is reasoned that any organically grown fruits and/or vegetables could be a source of pectin.

The juice industry (the source of citrus peel and apple pomace) is one of the primary sources of pectins. One concern is the production volume needed to produce an organically grown source of pectin.[298] **Whether or not the organic juice industry can provide enough organic citrus peel, apple pomace, or other organic fruits or vegetables byproducts to meet the organic pectin needs of the organic industry is insufficiently addressed in the 2009 TR, and not at all in the 2010 Supplemental Report** (compiled by the NOP's Technical Services Branch) **or in the 2015 Limited Scope TR** (compiled by OMRI for the NOP)**.** Without an incentive for manufacturers to use organic fruit and/or vegetable sources for the manufacture of pectin, only sources obtained from chemical agriculture will likely ever be used.

Pectins, a complex group of polysaccharides, act as cellular binders in the peel of many different fruits and vegetables. Pectins are mainly used as gelling agents but can also act as thickeners, water binders, and stabilizers.

Pectins have been divided into two groups in the market: those containing more than 50% esterification (high methoxy pectin, HMP) and those containing less than 50% esterification (low methoxy pectin, LMP).[299]

Low methoxy pectins form thermoreversible gels in the presence of calcium ions at low pH (pH 3-4.5) and thus need little to no sugar to gel.[300] LMP is used in reduced-sugar and sugar-free jams and other low-sugar products.

Most of the "natural" pectins are HMP, with a few exceptions such as sunflower pectin, which does not appear significantly developed commercially. There are no other known viable commercial natural sources of non-amidated low methoxyl pectin. As such, non-

[297] 2009 TR – Non-amidated low-methoxyl Pectin. Page 5, line 212-213
[298] Ibid. Page 6, line 236-241
[299] Ibid. Page1, line 6-8
[300] Ibid. Page 1, line 13-15

amidated low methyl pectins are generally obtained from high methoxyl pectins by chemical demethylation.[301]

Demethylation is a chemical process. There are four methods of demethylation depending on the agents used: acids, alkalis, enzymes, and ammonia in alcohol. Acid demethylation is commonly used to manufacture LMP.[302] However, enzymatic demethylation is a viable commercial alternative to manufacture LMP and should be considered as such by the NOSB.

Pectins are usually diluted with sugars such as dextrose (glucose) or sucrose for standardization purposes.[303] They are also commonly formulated with several ancillary substances, specifically food grade buffer salts for pH control and specific setting characteristics. In some instances, sulfur dioxide may be added as a preservative.[304] **Dextrose and sucrose are often extracted from GMO sources such as beets or corn; therefore, only organic sugars should be used in pectin formulations. Several of the buffer salts are not on the National List and should not be included in formulations; thus, an annotation highlighting these requirements should be added to the pectin listing on the National List.**

Handling Subcommittee deliberations

During the discussion preceding the vote, the subcommittee mentioned the receipt of the 2015 Limited Scope TR that examined the use of ancillary substances in pectin formulations. The lead member for this material, Zea Sonnabend, stated that she would write an ancillary substances proposal.

Vote:
Motion to remove pectin (non-amidated forms only) from §205.606
Motion by: Zea Sonnabend
Seconded by: Jean Richardson
Additional Discussion: none
Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0

CONCLUSION

The Cornucopia Institute **supports the relisting of pectin – (non-amidated forms only) under §205.606(s)** with the recommendation that the availability of organic sources be further investigated and that annotations be added requiring that:

- ***Only*** organic sugar and ancillary substances listed on the National List be allowed in pectin formulations.
- ***Only*** low-methoxy pectins produced via an ***enzyme-mediated*** process be allowed for use in foods labeled organic.

[301] 2009 TR – Non-amidated low-methoxyl Pectin. Page 6, line 236-241
[302] Ibid. Page 5, line 190-192
[303] 2015 Limited Scope TR – Pectin. Page 1, line 29-50
[304] Ibid. Page 1, line 29-50

Tocopherols – 2017 Sunset

SUMMARY

The Cornucopia Institute **opposes the relisting of tocopherols derived from vegetable oil when rosemary extracts are not a suitable alternative,** under 7 CFR §205.605(b) Synthetics allowed, and **supports the listing** of **tocopherols** under 7 CFR §205.605(a) Nonsynthetics allowed, with an annotation stating "Only natural tocopherols extracted without synthetic solvents."

Rationale:

- Tocopherols are natural compounds extracted from edible vegetable oils such as soybean, rapeseed sunflower, corn and cottonseed oils.
- Tocopherols are extracted from the distillate resulting from the deodorization of vegetable oils via several steps which can include extraction with volatile organic solvents.
- Hexane is a commonly used solvent to extract tocopherols from soybean oil. Other solvents may include ethanol, isopropanol alcohol, acetone, isopentatne, isohexane, trichloroethylene, or petroleum ether.
- The main sources of tocopherols are conventionally grown oils. In reviewing the impact of their manufacture, the NOSB must consider the consequences of raising the non-organic crops used to produce it.
- Many oils used in the production of tocopherols are often obtained from GMO crops.
- **Commercial sources of natural tocopherols extracted without synthetic solvents exist.**
- Tocopherols are commonly formulated with ancillary substances; only handling materials on the National List not obtained via excluded methods should be used.

DISCUSSION

Tocopherols possess vitamin E activity and are an antioxidant ingredient mainly used for the stabilization of food products containing fats or oils susceptible to oxidation damages resulting in off-flavor (rancidity). Their action helps preserve the taste and nutritional value of the food. They are used as additives in a variety of food including dairy products, cereals, frozen green vegetables, margarine, fresh and frozen sausages, vegetable oils, soft drinks, snacks and nuts, salad dressings, soup bases, seasonings, dehydrated potatoes, processed meats and poultry, and baked products.[305]

Tocopherols are a group of fat-soluble phenolic antioxidants naturally occurring in a variety of plant species, encompassing cereal grains, oilseeds, nuts, and vegetables.[306]

The term "tocopherols" refers to structurally similar compounds that occur in nature in four forms: alpha-, beta-, gamma-, and delta-tocopherol. Tocopherols derived from plant

[305] Limited Scope TR, 2015 - Tocopherols. Page 4, line 109-115

[306] Burdock, G.A. 1997. Tocopherols. In: Encyclopedia of Food and Color Additives, Volume III. CRC Press, Boca Raton, FL, pp. 2801-2803.

products are often referred to as "mixed tocopherols" because the mixture contains all four forms of tocopherol (CIR, 2002). [307]

Human health concerns

Tocopherols used as antioxidants in food are generally extracted from oil distillate, a deodorization by-product of vegetable oils (e.g., soybean, canola, sunflower, corn, cottonseed).[308]

Tocopherols need to be separated from the other compounds in the oil distillate by a series of extraction and refining steps which can include **solvent extraction, chemical treatment, crystallization, complexation, and vacuum or molecular distillation**.[309]

Soybean oil is often a source of mixed tocopherols, which are obtained from soybean oil by solvent extraction, **hexane** being a commonly-used solvent. Other solvents may include ethanol, isopropanol, acetone, isopentane, isohexane, trichloroethylene, or petroleum ether.[310] In addition, various organic solvents such as hexane are traditionally used during extraction of tocopherols from plant products.[311]

Soybean oil is often extracted using hexane. A 2009 study by The Cornucopia Institute found hexane residues in soybean oil.[312] Hexane is a neurotoxic petrochemical solvent listed as a hazardous air pollutant by the EPA, and is "Harmful or fatal if swallowed" according to the MSDS.[313]

The oil is first extracted using hexane, then the oil distillate, a by-product of oil refining, is further processed with hexane to extract tocopherols. So, the oil distillate would most likely contain hexane residues, which would be further augmented during the hexane extraction of mixed tocopherols from soybean oil and potentially from any other edible oils whenever hexane is used.

Considering the toxicity of hexane, and of some of the other solvents used, and the fact that extraction using volatile solvents is a prohibited method under the organic regulations, it would be wise to ensure that only natural tocopherols obtained without solvents are used as antioxidants in processed foods to prevent long-term chronic exposure to hexane.

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[307] CIR (Cosmetic Ingredient Review). 2002. Final Report on the Safety Assessment of Tocopherol, Tocopheryl Acetate, Tocopheryl Linoleate, Tocopheryl Linoleate/Oleate, Tocopheryl Nicotinate, Tocopheryl Succinate, Dioleyl Tocopheryl Methylsilanol, Potassium Ascorbyl Tocopheryl Phosphate, and Tocophersolan. *International Journal of Toxicology* 21: 51-116. Available online at http://ijt.sagepub.com/content/21/3_suppl/51

[308] Burdock, G.A. 1997. Tocopherols. In: Encyclopedia of Food and Color Additives, Volume III. CRC Press, Boca Raton, FL, pp. 2801-2803.

[309] Limited Scope TR, 2015 - Tocopherols. Page 4, line 87-89

[310] Limited Scope TR, 2015 - Tocopherols. Page 8, line 308-313

[311] Ogbanna, J.C. 2009. Microbiological production of tocopherols: current state and prospects. Applied 787 Microbiology and Biotechnology 84(2): 217-225.

[312] http://www.cornucopia.org/2009/05/soy-report-and-scorecard/

[313] Registry, A., & Health, N. (2013). Public Health Statement for n-Hexane. Retrieved from http://www.eoearth.org/view/article/51cbeebe7896bb431f699f7a

Alternatives and essentiality

In 2014 there were already **several sources of non-solvent extracted natural tocopherols**. This was pointed out in the minority report on the tocopherols proposal for aquaculture, which was deliberated at the spring 2014 NOSB meeting:

> "The minority also has concerns about the unnecessary presence of volatile synthetic solvents in tocopherols. The Livestock Subcommittee received a letter from Oh Oh Organics supporting the consistent availability of natural tocopherols extracted without synthetic solvents. The letter states, "*I have sold* ***Non-GMO, non-solvent extracted tocopherol since 2005****. Both BASF, an international ingredient manufacturer out of Germany and BTSA, a company specializing in non-GMO Tocopherols supply this material. It is consistently available and is broadly used in the food, cosmetic and household cleaning business. Additionally I have seen ISO certified documents for a supplier in China...so, I believe it available around the world*."

Other considerations

Many of the oils from which the tocopherols are extracted are often obtained from GMO crops, including canola, soy, corn, cottonseed. When reviewing this material, the NOSB must consider whether the manufacturing base was obtained from excluded methods.

The main sources of tocopherols are conventionally grown oils. In reviewing the impact of their manufacture, the NOSB must consider the consequences of raising the non-organic crops used to produce these oils.

The main reason that the use of rosemary oil is not always desirable, in spite of its effectiveness as an antioxidant, is that it may impart off flavors or fragrances to certain products, which can be found objectionable by customers.

Tocopherols are commonly formulated with ancillary substances[314]**;** only handling materials listed on the National List and additionally not obtained via excluded methods should be used in tocopherols formulations.

Handling Subcommittee discussions and vote

<u>What is troubling is that the issue of solvent extraction</u> and potential solvent residues in tocopherols, even though pointed out in both the 2015 TR and the 2013 Aquaculture TR, was not even breached when the Handling Subcommittee discussed tocopherols**.**

What the subcommittee focused on was the issue of essentiality, pointing to the strong industry support shown at the Spring 2015 NOSB meeting. It is likely that the industry is going to support the relisting of this product, but that should not unduly influence the

[314] Limited Scope TR, 2015 - Tocopherols. Pages 5-6, line 175-191

decision of the subcommittees. After all, the role of the subcommittees and NOSB is to thoroughly review without bias any sunsetting materials to ensure that the OFPA requirements are met.

Vote to remove from National List**:**

Motion by: Tracy Favre
Seconded by: Ashley Swaffar
Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse:

CONCLUSION

The Cornucopia Institute **opposes the relisting of tocopherols** under **§205.605(b)** Synthetics allowed, but supports the listing of tocopherols under **§205.605(a)** Nonsynthetics allowed, **with an annotation stating "Only natural tocopherols extracted without synthetic solvents"**.

Furthermore, the **NOSB should encourage the production of organic tocopherols** by placing an expiration date on the §205.605(a) listing.

Waxes, non-synthetic – 2017 Sunset

Table 3: Comparing NOP-approved Fruit and Vegetable Waxes

Name	Description	Advantages	Disadvantages
Orange shellac, unbleached	205.606 -Non-organically produced agricultural products allowed as ingredients in or on processed products labeled as "organic," only when the product is not available in organic form. -Major component in fruit coatings. Also used in vegetable coating, as a coating or glaze on candy, and to coat enteric pills (supplement and pharmaceutical industry).	-Low oxygen and CO_2 permeability, moderately resistant to water vapor. -Shiniest coating; water insoluble, UV-resistant. -Prevents some type of post-harvest decay by supporting populations of bio-control organisms[315] -There are commercially available shellac-based fruit coating products in which the shellac is combined only with substances permitted by organic regulations.[316,317]	-Low oxygen and CO_2 permeability. Can cause low oxygen and excessive accumulation of CO_2 leading to fermentation and off-flavors.[318] -Not available in organic form. -Often formulated with other waxes as well as with various ancillary substances.
Carnauba wax	205.605(a) -Wax – Non-synthetic. Nonagricultural (nonorganic) substance allowed as ingredient in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))." -Historically used in organic food processing as a component of fruit and vegetable waxes and candy coating. -As a fruit coating, it is always formulated with other ingredients (other	-Low oxygen and moisture permeability, but more permeable to O_2 and CO_2 than shellac or wood rosin.[319] -Protect flavor better than the other waxes. Has antifungal activity and prevents some post-harvest fungal-based decay. -Available in organic form, and in commercial formulations compliant for use as fruit waxes on organic foods.[320]	-Not as shiny coating. -Often formulated with other waxes such as shellac, wood rosin, beeswax, and candelilla for best performance.

[315] McGuire, R G, and R D Hagenmaier. "Shellac formulations to reduce epiphytic survival of coliform bacteria on citrus fruit postharvest." *Journal of Food Protection* 60, no. 11 (2001): 1756-1760.
[316] OMRI. *OMRI Products Database.* Edited by Organic Materials Review Institute. Eugene, October 22, 2013.
[317] 2014 TR – Orange shellac. Page 5, lines 181-183
[318] Krochta, John M, Elizabeth A. Baldwin, and Myrna O. Nisperos-Carriedo. *Edible Coatings and Films to Improve Food Quality.* Boca Raton, FL: CRC Press LLC, 1994
[319] Hagenmaier, R. D., and P. E. Shaw. "Gas Permeability of Fruit Coating Waxes." *Journal of the American Society for Horticultural Science*, 1992: 105-109.
[320] OMRI. *OMRI Products Database.* Edited by Organic Materials Review Institute. Eugene, October 22, 2013.

	waxes, and ancillary substances).		
Wood rosin	205.605(a) -Wax – Non-synthetic. Nonagricultural (nonorganic) substance allowed as ingredient in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))." -Wood rosin is used in organic food processing exclusively as a fruit coating, and for this purpose is always formulated with other ingredients (other waxes, and ancillary substances).	-Low oxygen and CO_2 permeability, moderately resistant moisture. -Shiny coating. Delay or prevent decay of coated fruits.* -Currently there are no known commercially available wood rosin-based fruit coating products in which the rosin is combined only with substances permitted by organic regulations.[321]	-Limited resistance to water vapor. -Low oxygen permeability can cause low oxygen and excessive accumulation of CO_2 leading to fermentation and off-flavors.[322] -Exclusively used as a fruit coating. Almost always formulated with other ingredients for best performance. -Not available in organic form.

*All fruit waxes can, to some extent, prevent post-harvest decay by providing a physical barrier to likely disease vectors.

Orange Shellac, unbleached

SUMMARY

The Cornucopia Institute remains neutral as to the relisting of unbleached orange shellac under 7 CFR §205.606 as a fruit and vegetable coating. Its purpose is to provide gloss, prevent moisture loss, and slow down the respiration rate of the coated fruit or vegetable thus increasing shell life and improving cosmetic appearance.

Even though annotations are not allowed under the NOP sunset provisions (decided unilaterally, breaking from precedent, and without input of the NOSB), we believe it is important to add an annotation to the effect that only ancillary substances approved for organic production be allowed in shellac-based coatings. Indeed, orange shellac is widely processed with alcohols, fatty acids, soaps, solvents, and may contain wood rosin, carnauba wax, dyes, plasticizers, preservatives, fungicides, growth regulators, etc.[323] Morpholine, an emulsifier commonly utilized in shellac-based coatings, is a known precursor of N-nitrosomorpholine, a **carcinogen**.[324] It is not allowed as an ingredient of wax coating for fruits in the European Union.[325]

[321] 2014 TR – Wood rosin. Page 4, lines 155-157
[322] Krochta, John M, Elizabeth A. Baldwin, and Myrna O. Nisperos-Carriedo. *Edible Coatings and Films to Improve Food Quality.* Boca Raton, FL: CRC Press LLC, 1994
[323] 2014 TR – Orange shellac. Page 4-5, lines 159-17
[324] Morpholine. Scientific Analysis Laboratories LTD
[325] http://nwhort.org/?s=Morpholine

There are commercially available shellac-based fruit coating products in which the shellac is combined only with substances permitted by organic regulations.[326,327]

Rationale:

- Orange shellac, unbleached is a natural bio-adhesive polymer produced by the lac insect.
- As a non-toxic natural resin, shellac is used in the food and pharmaceutical industries as an edible coating (or an ingredient thereof) for processed foods, produce, candies, and pharmaceuticals.
- Few effective alternatives exist, besides the other non-synthetic waxes, for enhancing appearance and preventing weight loss, the main functions provided by fruit waxes.
- Shellac manufacture does not appear to have major adverse environmental effects.[328]
- However, the addition of various ancillary substances not approved for organic production in shellac-based coatings is problematic as some of these substances may be derived from GMO crops, or be synthetic and potentially toxic.

DISCUSSION

Orange shellac, unbleached is currently classified under §205.606(r) as a non-organically produced agricultural product allowed as an ingredient in or on processed products labeled as "organic."

It is used as a fruit and vegetable coating as well as for pharmaceutical (lozenges, capsules, tablets) and confectionary (glazes on chocolates, coffee beans, candy, etc.) applications. Its primary use is as a fruit coating along with wood rosin and carnauba wax. It is commonly used as a component of fruit waxes, along with other substances that may or may not be approved for organic production (e.g., morpholine).

Human health concerns

There are no studies indicating adverse effect on human health due to orange shellac. A small number of people may be allergic to shellac.[329,330]

Environmental health

There are no major environmental consequences associated with the production and processing of shellac.[331]

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[326] OMRI. *OMRI Products Database.* Edited by Organic Materials Review Institute. Eugene, October 22, 2013.
[327] 2014 TR – Orange shellac. Page 5, lines 181-183
[328] 2014 TR – Orange shellac. Page11, lines 427-428
[329] http://www.webmd.com/vitamins-supplements/ingredientmono-90-shellac.aspx?activeingredientid=90&activeingredientname=shellac
[330] Mary Ann Liebert Publication. "Final Report on the Safety Assessment of Shellac." Journal of the American College of Toxicology, 1986: 309-327.
[331] 2014 TR – Wood rosin. Page 4, lines 155-157

Efficacy

Wax formulations are used to improve attractiveness and extend post-harvest shelf life by reducing respiration and ethylene production, preventing transpiration of moisture with its resulting weight loss, basically slowing down ripening thus slowing down spoilage.

Shellac has the unique ability to provide high gloss with relatively thin coatings, one of the reasons why it is approved by the FDA as a food safe coating even though it is not listed as GRAS. The FDA allows its use as an additive on food products. Shellac coatings protect against high humidity and temperatures, have low permeability to gases, and moderate permeability to water vapor.

Wood rosin, carnauba wax, beeswax, and candelilla wax are four different non-synthetic substances that could be utilized in place of orange shellac as a component of fruit waxes, each with its own advantages and disadvantages, including shine, gas permeability, cost, etc. Only wood rosin and carnauba wax are permitted as non-organic ingredients in food waxes used on organic fruits.

Several non-synthetic and agricultural alternatives have been studied to some extend but all are dependent for effectiveness on their formulation; however, there is little evidence that alternatives exist that adequately match the desirable characteristics of waxes and resins.[332]

Closing comments

The 2002 TAP review and the 2014 TR both question the compatibility of shellac and other fruit and vegetable coatings with organic principles and had serious concerns about the ancillary substances used in most shellac-based fruit and vegetable coatings. The reviewers point out that consumers do not expect organic produce to be waxed, especially without notifying consumers, some of whom may be allergic to shellac or to the ancillary ingredients mixed with it in the coating formulations.

The FDA states that by federal law, produce shippers and supermarkets in the United States are required to label fresh fruits and vegetables that have been waxed so consumers will know whether the produce they buy is coated. The consumer is further advised to "Watch for signs that say: *'Coated with food-grade vegetable-, petroleum-, beeswax-, or shellac- based wax or resin, to maintain freshness.'*"[333] However, the labels or signs are posted in the general produce area of supermarkets, thus used in a non-targeted manner (that is, the produce coated are not specified) and the ingredients of the coatings are <u>not</u> listed.

Since these materials are generally used to preserve fruits and vegetables for longer periods of transportation, storage and retailing, requiring labels would potentially give a

[332] 2014 TR – Orange shellac. Page11-12, lines 472-475
[333] http://www.fda.gov/food/resourcesforyou/consumers/ucm114299, bottom of page.

competitive advantage to locally produced and marketed organic produce (which, for many cultivars, are generally sold uncoated).

Both the 2014 TR and the 2002 TAP mention a large number of possible ancillary substances, including the potentially toxic morpholine.[334] It is important to identify which of these ancillary substances are allowed in orange shellac-based coatings used on organic produce.

Although annotations are currently not allowed under the NOP sunset provisions, we believe it is important to add an annotation requiring 1) The labeling of coated organic produce with the components listed, and 2) That only ancillary substances approved for organic use be allowed in shellac-based coatings. This is a reasonable request and expectation considering that produce waxing or coating is generally not associated with organic practices. As noted earlier, there are commercially available shellac-based fruit coating products in which the shellac is combined only with substances permitted by organic regulations.

Handling Subcommittee deliberations and vote

The subcommittee mentioned the ancillary substance used in coating formulations and stated: *"Since there are fully compliant organic formulations on the market, this does not need further action*." This statement misses the point: **there may be compliant organic formulations but there are no annotations requiring the use** of these compliant formulations in organic fruit and vegetable coatings. The subcommittee also discussed the issue of wax coating of organic vegetables, brought up in public comments, which is a practice not expected by organic consumers, and the desire for labeling coated fruits and vegetables. The HS meeting notes state:

> "*The Handling Subcommittee recognizes this issue and urges voluntary labeling of produce coatings, but is unable to put forward an additional labeling annotation*."

It is the position of The Cornucopia Institute that the adoption by the NOP of a prohibition on annotations at Sunset violates the traditional collaborative process that has always taken place between the NOSB and industry stakeholders. Furthermore, the prohibition is not legally mandated. The board can pass an annotation at its option and should be on record, accordingly, whenever such action is necessary.

Vote:

Motion to remove Orange Shellac from 205.606(r)
Motion by: Zea Sonnabend
Seconded by: Harold Austin
Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

[334] 2014 TR – Orange shellac. Page 4-5, lines 159-173

CONCLUSION

At this time, The Cornucopia Institute is neutral as to the relisting of orange shellac, unbleached under §205.606. Cornucopia would support its relisting with an annotation to the effect that organic sources for ancillary substances must be used unless they are not commercially available, in which case only ancillary substances approved for organic use be allowed in shellac-based coatings, with the additional requirement that consumers be informed of the presence of a coating on organic produce (fruits and vegetables) and its ingredients listed.

Wood Rosin

SUMMARY

The Cornucopia Institute remains neutral as to the relisting of wood rosin under 7 CFR §205.605(a) as a fruit coating. Its purpose is to provide gloss, prevent moisture loss, and slow down the respiration rate of the coated fruit or vegetable thus increasing shell life and improving cosmetic appearance.

Even though annotations are not allowed under the NOP sunset provisions (decided unilaterally, breaking from precedent, and without input of the NOSB), we believe it is important to add an annotation to the effect that only ancillary substances approved for organic production be allowed in wood rosin-based coatings. Indeed, wood rosin is widely processed with alcohols, fatty acids, soaps, solvents, and may contain coumarone indene resin (synthetic resin), shellac, carnauba wax, dyes, oxidized polyethylene, plasticizers, anti-foam agents, preservatives, fungicides, growth regulators, etc.[335] Morpholine, an emulsifier commonly utilized in shellac-based coatings, is a known precursor of N-nitrosomorpholine, a **carcinogen**.[336] It is not allowed as an ingredient of wax coating for fruits in the European Union.[337]

Rationale:

- Wood rosin is a resin derivative obtained from two species of pine trees.[338]
- As a non-toxic natural resin, wood rosin is used in organic processing and handling almost exclusively as an ingredient in fruit wax coatings.[339, 340]

[335] 2014 TR – Wood rosin. Page 4, lines 146-155
[336] Morpholine. Scientific Analysis Laboratories LTD
[337] http://nwhort.org/?s=Morpholine
[338] 2014 TR – Wood rosin. Page 2, lines 50-53
[339] Ibid. Page 10, lines 462-470
[340] Ibid. Page 4, lines 172-173

- Few effective alternatives exist besides the other non-synthetic waxes for enhancing appearance and preventing weight loss, the main functions provided by fruit waxes.[341]
- However, the addition of various ancillary substances not approved for organic production in wood rosin-based coatings is problematic as some of these substances may be derived from GMO crops, or be synthetic and potentially toxic.[342]

DISCUSSION

Wood rosin is currently classified under §205.605, Non-agricultural (non-organic) substances allowed as ingredients in or on processed products labeled as "organic" or made with organic (specified ingredients or food group(s))." (a) Non-synthetics allowed: Waxes – non-synthetic.

Its primary use is as a fruit coating (mainly citrus) along with shellac and carnauba wax. It is commonly used as a component of fruit waxes, along with other substances that may or may not (e.g. morpholine) be approved for organic production.

Human health concerns

Under occupational conditions, wood rosin (or the products containing it) can be a dermatological irritant (allergy) and is linked to asthma.[343] There is no documented incidence of dermatitis due to consuming or handling wood rosin-based fruit waxes.[344]

Environmental health

Rosin is obtained by solvent extraction, a potential source of environmental effects. The solvent likely used has been surmised by the EPA to be methyl isobutyl ketone (MIBK), a relatively toxic solvent classified by the EPA as a group D substance with no data as to human carcinogenicity.[345] The industry claims that all solvents are recovered, and that the air emissions, except those permitted by the EPA, are collected and treated in chemical scrubbers or thermal oxidizers.[346] Due to its lack of vapor pressure, wood rosin is not found in the atmosphere and ecotoxicology data show that it does not adversely affect aquatic environments.

Efficacy

Wax formulations are used to improve attractiveness and extend post-harvest shelf life by reducing respiration and ethylene production, preventing transpiration of moisture with its resulting weight loss, basically slowing down ripening thus slowing down spoilage.

[341] Ibid. Page 10, lines 477-478
[342] Wood rosin. Page 4, lines 146-155
[343] 2014 TR – Wood rosin. Page 9, lines 429-431
[344] Ibid. Page 9, lines 443-444
[345] http://www.epa.gov/ttnatw01/hlthef/methyl-k.html
[346] 2014 TR – Wood rosin. Page 9, lines 405-408

Wood rosin provides a desirable gloss to citrus and is an effective barrier to prevent water vapor loss. It is used extensively as a component of fruit waxes. It is approved by the FDA as an ingredient in citrus wax coating even though it is not listed as GRAS. The FDA also allows its use as an indirect food additive. Wood rosin coatings decrease gas exchanges between the fruit and its environment, have moderate permeability to water vapor, delay ripening and provide a barrier protecting the fruit from post-harvest diseases.

Orange shellac, carnauba wax, beeswax, and candelilla wax are four different non-synthetic substances that could be utilized in place of wood rosin as a component of fruit waxes, each with its own advantages and disadvantages, including shine, gas permeability, cost, etc. Only orange shellac and carnauba wax are permitted as non-organic ingredients in food waxes used on organic fruits.[347]

Several non-synthetic and agricultural alternatives have been studied to some extend but all are dependent for effectiveness on their formulation; however, there is little evidence that alternatives exist that adequately match the desirable characteristics of waxes and resins.[348]

Closing comments

The 2014 TR question the compatibility of wood rosin and other fruit and vegetable coatings with the organic principles and had serious concerns about the ancillary substances used in most wood rosin-based fruit and vegetable coatings. The reviewers point out that consumers do not expect organic produce to be waxed, especially without notifying consumers, some of whom may be allergic or susceptible to wood rosin or to the ancillary ingredients mixed with it.

The FDA states that by federal law, produce shippers and supermarkets in the United States are required to label fresh fruits and vegetables that have been waxed so consumers will know whether the produce they buy is coated. The consumer is further advised to "Watch for signs that say: *'Coated with food-grade vegetable-, petroleum-, beeswax-, or shellac- based wax or resin, to maintain freshness.*"[349] However, the labels or signs are posted in the general produce area of supermarkets, thus used in a non-targeted manner (that is, the produce coated is not specified) and the ingredients of the coatings are not listed.

Since these materials are generally used to preserve fruits and vegetables for longer periods of transportation, storage and retailing, requiring labels would potentially give a competitive advantage to locally produced and marketed organic produce (which, for many cultivars, are generally sold uncoated).

[347] 2014 TR – Wood rosin. Page 11, lines 510-514
[348] 2014 TR – Orange shellac. Page11-12, lines 472-475
[349] http://www.fda.gov/food/resourcesforyou/consumers/ucm114299, bottom of page.

The 2014 TR mention a large number of possible ancillary substances, including the potentially toxic morpholine.[350] It is important to identify which of these ancillary substances are allowed in wood rosin-based coatings used on organic fruits. Although annotations are currently not allowed under the NOP sunset provisions, we believe it is important to add an annotation requiring 1) The labeling of coated organic produce with the components listed, and 2) That only ancillary substances approved for organic use be allowed in wood rosin-based coatings. This is a reasonable request and expectation since produce waxing or coating is generally not associated with organic practices. In addition, there are commercially available ancillary substances permitted by organic regulations for use with wax and resin coatings.[351]

Handling Subcommittee deliberations and vote

It was noted that a technical correction needs to be made to change the listing from "Wood Resin" to "Wood Rosin", the correct term. The subcommittee recommends the correction be made.

The subcommittee mentioned the public concerns regarding ancillary substances, in particular morpholine used in coating formulations with Wood Rosin and stated: *"Since there is ample availability of formulations of other fruit coatings that are fully NOP compliant for ingredients according to the TR, this issue does not need further action*." This statement misses the point, <u>there may be compliant organic formulations but there are no annotations requiring the use</u> of these compliant formulations in organic fruit and vegetable coatings.

The subcommittee also discussed the issue of wax coating of organic vegetables, brought up in public comments, which is a practice not expected by organic consumers, and the desire for labeling coated fruits and vegetables. The HS meeting notes state:

> "*The Handling Subcommittee recognizes this issue and urges voluntary labeling of produce coatings, but is unable to put forward an additional labeling annotation*."

It is the position of The Cornucopia Institute that the adoption by the NOP of a prohibition on annotations at Sunset violates the traditional collaborative process that has always taken place between the NOSB and industry stakeholders. Furthermore, the prohibition is not legally mandated. The board can pass an annotation at its option and should be on record, accordingly, whenever such action is necessary.

<u>Vote:</u>

Motion to remove Wood Rosin from 205.605(a)
Motion by: Zea Sonnabend
Seconded by: Harold Austin
Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

[350] 2014 TR – Orange shellac. Page 4-5, lines 159-173
[351] 2014 TR – Wood rosin. Page 4, lines 157-165

CONCLUSION

At this time, The Cornucopia Institute is neutral as to the relisting of wood rosin under §205.605(a). Cornucopia would support its relisting with an annotation to the effect that organic sources for ancillary substances must be used unless they are not commercially available, in which case only ancillary substances approved for organic use be allowed in wood rosin-based coatings, with the additional requirement that consumers be informed of the presence of a coating on organic produce (fruits and vegetables) and its ingredients listed.

Carnauba Wax

SUMMARY

The Cornucopia Institute remains neutral as to the relisting of carnauba wax under 7 CFR §205.605a as a fruit coating. Its purpose is to provide gloss, prevent moisture loss, and slow down the respiration rate of the coated fruit or vegetable thus increasing shell life and improving cosmetic appearance.

Even though annotations are not allowed under the NOP sunset provisions (decided unilaterally, breaking from precedent, and without input of the NOSB), we believe it is important to add an annotation to the effect that only ancillary substances approved for organic production be allowed in carnauba-based coatings. Indeed, carnauba is widely processed with alcohols, fatty acids, soaps, solvents, and may contain coumarone indene resin (synthetic resin), shellac, wood rosin, dyes, oxidized polyethylene, plasticizers, anti-foam agents, preservatives, fungicides, growth regulators, etc.[352] Morpholine, an emulsifier commonly utilized in shellac-based coatings, is a known precursor of N-nitrosomorpholine, a **carcinogen**.[353] It is not allowed as an ingredient of wax coating for fruits in the European Union.[354]

Rationale:

- Carnauba wax is a natural wax obtained from the carnauba palm.[355]
- As a non-toxic natural wax with a GRAS listing, carnauba is used in organic processing and handling almost exclusively as an ingredient in fruit and vegetable wax coatings.[356]
- It is allowed for organic handling and processing by the prevalent organic standards (U.S., EU, Canada, JAS, and IFOAM).

[352] 2014 TR – Wood rosin. Page 4, lines 146-155
[353] Morpholine. Scientific Analysis Laboratories LTD
[354] http://nwhort.org/?s=Morpholine
[355] 2014 TR – Carnauba wax. Page 1, lines 33-35
[356] Ibid. Page 2, lines 65-66

- Few effective alternatives exist besides the other non-synthetic waxes for enhancing appearance, reducing moisture and weight loss, and postponing decay, the main functions provided by fruit waxes.[357], [358]
- However, the addition of various ancillary substances not approved for organic production in carnauba wax-based coatings is problematic as some of these substances may be derived from GMO crops, or be synthetic and potentially toxic.[359]

DISCUSSION

Carnauba wax is currently classified under §205.605, Non-agricultural (non-organic) substances allowed as ingredients in or on processed products labeled as "organic" or made with organic (specified ingredients or food group(s))." (a) Non-synthetics allowed: Waxes – non-synthetic.

Its primary use in organic food handling and processing is as a component of fruit and vegetable waxes along with other substances that may or may not be approved for organic production (e.g., morpholine), in candy coatings and as an ingredient of edible coatings for nuts.

Human health concerns

There are no toxicological concerns associated with the use of carnauba wax as a fruit or vegetable coating or a food additive.[360]

Environmental health

There are no reported environmental impacts due to the production of the carnauba wax.[361]

Efficacy

Wax formulations are used to improve attractiveness and extend post-harvest shelf life by reducing respiration and ethylene production, preventing transpiration of moisture with its resulting weight loss, basically slowing down ripening thus slowing down spoilage.

Carnauba wax provides a desirable gloss to citrus and prevents weight loss. It is listed as GRAS by the FDA and is used extensively as a component of fruit and vegetable waxes. Carnauba-based coatings decrease gas exchanges between the fruit and its environment, have moderate permeability to water vapor, and delay ripening. They are effective in controlling post-harvest fungal diseases.

[357] 2014 TR – Wood rosin. Page 10, lines 477-478
[358] 2014 TR – Carnauba wax. Page 3, lines 110-112
[359] 2014 TR – Carnauba wax. Page 4, lines 149-167
[360] Ibid. Page 10-11, lines 467-500
[361] Ibid. Page 9-10, lines 437-461

Orange shellac, wood rosin, beeswax, and candelilla wax are four different non-synthetic substances that could be utilized in place of carnauba wax as a component of fruit waxes, each with its own advantages and disadvantages, including shine, gas permeability, cost, etc. Only orange shellac and wood rosin are permitted as non-organic ingredients in food waxes used on organic fruits.[362]

Several non-synthetic and agricultural alternatives have been studied to some extend but all are dependent for effectiveness on their formulation; however, there is little evidence that alternatives exist that adequately match the desirable characteristics imparted by waxes and resins.[363]

Closing comments

The compatibility of carnauba wax and other fruit and vegetable coatings with the organic principles was questioned by the authors of the 2014 TR. In addition, serious concerns about the ancillary substances used in most carnauba-based fruit and vegetable coatings were raised. The reviewers point out that organic produce is not expected to be waxed, especially without notifying consumers, some of whom may be allergic to carnauba wax or susceptible to the ancillary ingredients mixed with it in the coating formulations.

The FDA states that by federal law, produce shippers and supermarkets in the United States are required to label fresh fruits and vegetables that have been waxed so consumers will know whether the produce they buy is coated. The consumer is further advised to "Watch for signs that say: *'Coated with food-grade vegetable-, petroleum-, beeswax-, or shellac- based wax or resin, to maintain freshness.*"[364] However, the labels or signs are posted in the general produce area of supermarkets, thus used in a non-targeted manner (that is, the produce coated is not specified) and the ingredients of the coatings are not listed.

Since these materials are generally used to preserve fruits and vegetables for longer periods of transportation, storage and retailing, requiring labels would potentially give a competitive advantage to locally produced and marketed organic produce (which, for many cultivars, are generally sold uncoated).

The 2014 TR sites a large number of possible ancillary substances, including the potentially toxic morpholine.[365] It is important to identify which of these ancillary substances are allowed in carnauba wax-based coatings used on organic produce.

Although annotations are currently not allowed under the NOP Sunset provisions, we believe it is important to add an annotations requiring 1) The labeling of coated organic produce with the components listed and 2) That only ancillary substances approved for organic use be allowed in wood rosin-based coatings. This is a reasonable request and

[362] 2014 TR – Carnauba wax. Page 12, lines 559-563
[363] 2014 TR – Orange shellac. Page11-12, lines 472-475
[364] http://www.fda.gov/food/resourcesforyou/consumers/ucm114299, bottom of page.
[365] 2014 TR – Carnauba wax. Page 4, lines 158-163

expectation considering that produce waxing or coating is generally not associated with organic practices. In addition, there are commercially available ancillary substances permitted by organic regulations.

Additional comment

According to the TR, commercial sources of organic carnauba wax are now available.

Moreover, the TR posits the possibility of changing the classification of carnauba wax from a "non-agricultural substance" to an "agricultural product" as defined by §205.2.[366] In its Sunset 2017 Review summary, the NOSB requested comments pertaining to this potential reclassification.[367]

Regardless of whether or not carnauba wax is listed as an agricultural product and removed from the National List, Cornucopia's position in regard to fruit and vegetable coatings remains the same. Coatings may not be compatible with organic principles and thus the customer must be informed of the presence of such coatings and the ingredients of the coatings must be listed. In addition, the issue of ancillary substances that are added to organic fruit and vegetable coatings needs to be addressed.

Handling Subcommittee deliberations and vote

The handling subcommittee, based on the information provided by the TR that Carnauba wax is an agricultural product and should be on §205.606, and states that a separate proposal will be submitted for that purpose.

The subcommittee mentioned the public concerns regarding ancillary substances, in particular morpholine used in coating formulations with Carnauba wax and stated: *"Since there is ample availability of formulations of other fruit coatings that are fully NOP compliant for ingredients according to the TR, this issue does not need further action*." This statement misses the point, there may be compliant organic formulations but there are no annotations requiring the use of these compliant formulations in organic fruit and vegetable coatings.

The subcommittee also discussed the issue of wax coating of organic vegetables, brought up in public comments, which is a practice not expected by organic consumers, and the desire for labeling coated fruits and vegetables. The HS meeting notes state:

> "*The Handling Subcommittee recognizes this issue and urges voluntary labeling of produce coatings, but is unable to put forward an additional labeling annotation*."

It is the position of The Cornucopia Institute that the adoption by the NOP of a prohibition on annotations at Sunset violates the traditional collaborative process that has always taken place between the NOSB and industry stakeholders. Furthermore, the prohibition is

[366] 2014 TR – Carnauba wax. Page 8, lines 338-340
[367] http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5110822

not legally mandated. The board can pass an annotation at its option and should be on record, accordingly, whenever such action is necessary.

Vote:

Motion to remove Carnauba wax from 205.605(a)
Motion by: Zea Sonnabend
Seconded by: Harold Austin
Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

CONCLUSION

At this time, The Cornucopia Institute is neutral as to the relisting of carnauba wax under §205.605(a). Cornucopia would support its relisting with an annotation to the effect that organic sources for ancillary substances must be used unless they are not commercially available, in which case only ancillary substances approved for organic use be allowed in carnauba-based coatings, with the additional requirement that consumers be informed of the presence of a coating on organic produce (fruits and vegetables) and its ingredients listed.

Xanthan Gum – 2017 Sunset

SUMMARY

The Cornucopia Institute **opposes the relisting of xanthan gum** under §205.605(b) Synthetics allowed.

Rationale:

- Xanthan gum is a natural polysaccharide derived by fermentation from the plant pathogenic bacteria *Xanthomonas campestris*.
- The fermentation medium is a complex sugar-containing solution that is often made with potentially allergenic substances such as corn, soy, dairy, or wheat.
- Xanthan gum has been **linked to** the development of **necrotizing enterocolitis** (NEC) in infants and intestinal distress such as **bloating and diarrhea** in sensitive individuals.
- Xanthan gum dust may cause respiratory distress such as nose and throat irritation and other flu-like symptoms in bakery workers (occupational exposure).
- Many of the substrates (sugars) used in the production of xanthan gum are often obtained from GMO crops.
- **Organic or natural agricultural substitutes exist**, including guar gum and locust bean gum, which are listed on the National List and are available commercially. Other alternatives such as chia seeds, flax seeds, and psyllium seed husks, often used in combination, are available commercially in organic forms.
- The main use of **xanthan gum is as a texturizer and stabilizer, uses that are not permitted by the organic regulations** as stated in §205.600(b)(4),

DISCUSSION

Xanthan gum is a largely indigestible polysaccharide derived by **fermentation from the phytopathogenic bacteria *Xanthomonas campestris***. It is produced by fermentation in a complex sugar-based nutrient broth, extracted via an involved and costly multi-steps process that necessitates the use of synthetic solvents.

It is used as a **thickener and texturizer** as well as a **stabilizing agent** in a variety of processed food. Due to its binding properties, xanthan gum can be used as a replacement for gluten in gluten-free foods.

Human health concerns

Animal and human studies showed no harmful effects from the ingestion of xanthan gum. However, in large doses it can stimulate the gut microbiome to significantly increase the bacterial production of short-chain fatty acids (SCFA).[368] While this is a positive action in adults, as SCFA are vital to colon health, it can lead to the development of necrotizing enterocolitis (NEC) in infants[369], who are inherently very sensitive to SCFA.[370] Thus,

[368] http://www.ncbi.nlm.nih.gov/pubmed/8329363
[369] http://well.blogs.nytimes.com/2013/02/04/warning-too-late-for-some-babies/?_r=0

xanthan gum appears to be able to alter the gut microbiome, and it is unclear at this time whether or not that alteration could be problematic over time.

Occupational exposure can lead to respiratory symptoms in workers.[371]

Xanthan gum may be derived from a variety of sources that are potential allergens, such as corn, wheat, dairy, or soy. Allergic responses may occur in sensitive individuals upon ingestion.[372]

Some people develop sensitivities to xanthan gum with gastrointestinal symptoms, including bloating, gas, and diarrhea. Other reactions include the triggering of migraine headaches and skin itchiness. Xanthan gum sensitivity symptoms can become more prevalent with increased exposure over time.[373]

The only Technical Review available is a TAP review dating 1995. One TAP reviewer, Steven Harper, thought it should be classified as a naturally derived substance. The two other TAP reviewers, Dr. Richard Theuer (a former agribusiness executive) and Bob Durst, reasoned that it should be classified as a synthetic allowed due to the processing requiring synthetic solvents and because it is manufactured as either the sodium, calcium, or potassium salt, a synthetic substance.

Considering the uncertainties as to the potential health effects of this substance, and the fact that the only TR available is a TAP review dating 1995, **it is advisable to request a new Technical Review**, which would help further evaluate this material before renewing it on the National List.

Alternatives and essentiality

The organic regulations state under §205.600(b)(4):

> The following criteria will be utilized in the evaluation of substances or ingredients for the organic production and handling sections of the National List:
>
> (b) in addition to the criteria set forth in the Act, any synthetic substance used as a processing aid or adjuvant will be evaluated against the following criteria:
> …
> (4) The substance's **primary use is not as a preservative or to recreate or improve flavors, colors, textures, or nutritive value lost during processing**, except where the replacement of nutrients is required by law; [emphasis added]

This regulation is consistent with NOSB's "Principles of Organic Production and Handling" and guidance on "Compatibility with a System of Sustainable Agriculture and Consistency with Organic Farming and Handling," which stresses the importance of maintaining the integrity, quality, and authenticity of organic products. Synthetic preservatives threaten these qualities by artificially extending shelf-life and making products appear fresher than

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[370] http://www.ncbi.nlm.nih.gov/pubmed/14962641
[371] https://www.ncbi.nlm.nih.gov/pubmed/2391577
[372] http://en.wikipedia.org/wiki/Xanthan_gum#Health
[373] http://www.celiac.com/articles/21710/1/Could-Xanthan-Gum-Sensitivity-be-Complicating-your-Celiac-Disease-Recovery/Page1.html

they actually are. Texturizers create artificial foods that lack the authenticity and integrity that consumers expect from organic foods. Consumers also expect superior nutrition from organic food that comes from its production in "an ecological production management system that promotes and enhances biodiversity, biological cycles, and soil biological activity,"[374] and artificial nutrients or additives without appreciable nutritional value are inconsistent with that expectation.

Thus, xanthan gum is incompatible with a system of organic production.

In addition, **xanthan gum is not essential as there are several substitutes** when used in baking, such as guar gum, locust bean gum (both on the National List), flax seed, chia seed, and psyllium seed husks, many of which can be used in combination. These are all available in organic forms.

Other considerations

Some commenters at the Spring 2015 NOSB meeting argued that xanthan gum should be considered as a non-synthetic and reclassified either under §205.605(a) *Nonsynthetics allowed*, or §205.606 *Nonorganic agricultural products*.

Xanthan gum is of microbial origin, but its manufacture as a sodium, potassium, or calcium salt clearly indicates that it **is a synthetic material and as such cannot be reclassified under §205.605(a).**[375]

The organic regulations define "agricultural products" (according to the OFPA definition) and "nonagricultural" (no OFPA definition) in §205.2:

> *Agricultural Products.* Any agricultural commodity or product, whether raw or processed, including any commodity of product derived from livestock that is marketed in the United States for human or livestock consumption (§2103(1)).
>
> *Nonagricultural Substance.* A substance that is not a product of agriculture, such as a mineral or a bacterial culture that is used as an ingredient in an agricultural product. **For the purposes of this part, a nonagricultural ingredient also includes any substance, such as gums, citric acid, or pectin, that is extracted from, isolated from, or a fraction of an agricultural product so that the identity of the agricultural product is unrecognizable in the extract, isolate, or fraction.** [Emphasis added.]

Therefore, the draft materials classification guidance, which considers **fermentation as a processing method** that does not change the classification of the substrate from agricultural to non-agricultural, is valid only if both the substrate and the fermentation product meet the definition of agricultural, and not of non-agricultural substances. Accordingly, pickles, wine, and cheese are all agricultural, but substances that are unrecognizable from the original substrate—such as glycerin, a product from the fermentation of cornstarch, or fructooligosaccharides (FOS), a product from the

[374] NOSB's "Principles of Organic Production and Handling"
[375] 1995 TAP review

fermentation of glucose, among others—are thus non-agricultural, as is xanthan gum, the product from the fermentation of a complex, sugar-based medium.

Many of the sugars and other substrates used in the manufacturing of xanthan gum are often obtained from GMO crops, including corn, soy, and sugar beet. When reviewing this material, the NOSB must consider whether the manufacturing base is obtained from excluded methods.

The main sources of substrates used in the manufacture of xanthan gum are from conventionally grown crops. In reviewing the impact of their manufacture, the NOSB must consider the consequences of growing the non-organic crops used to produce these substrates.

Handling Subcommittee deliberations

During the first discussion about xanthan gum, the notes state: "The lead subcommittee member reviewing this material [Zea Sonnabend] indicated that the NOSB received many comments, the majority of which were in support of reclassification of Xanthan gum from 205.605(b) to 205.605(a)."

A more precise analysis would be that the majority of the commenters supported the relisting of xanthan gum to §205.605(b). Out of 12 written comments, 9 were in support of relisting, 2 were neutral, and 1 was opposed. One of the neutral comments questioned whether xanthan gum should be reclassified. Of the 9 in support of relisting (all industry related), **only 2 were also in support of reclassification** of xanthan gum to §205.605(a). These facts might lead the reader to a different conclusion than that of Ms. Sonnabend's statement as conveyed by the subcommittee meeting notes.

The draft classification guidance with regard to fermentation, which would affect whether or not xanthan gum should be reclassified, was also discussed, but the **NOP suggested moving forward with the review and not waiting for final guidance.**

The intervention by the NOP in this discussion is legally questionable, as it could be interpreted as an attempt to speed up the Handling Subcommittee decision-making process so as to ensure that the upcoming classification guidance with regard to products obtained by fermentation would not affect the outcome of the subcommittee deliberations regarding xanthan gum reclassification.

It should be noted that under the FACA law there are *"provisions to assure that the advice and recommendations of the advisory committee will not be inappropriately influenced by the appointing authority or by any special interest, but will instead be the result of the advisory committee's independent judgement."*

During the Handling Subcommittee's second discussion, Ms. Sonnabend pointed out that *"Xanthan gum, which **is non-synthetic** and listed on §205.605(b), is made in a similar manner as Gellan gum, which is listed on §205.605(a)"* [emphasis added]. Based on that observation, she proposed that the NOSB reclassify the material.

The comparison with gellan gum is inappropriate, as the classification of this material to §205.605(a) at the Fall 2008 meeting by the NOSB was controversial and the 2006 TR on which that decision was partly based was incomplete; it does not contain detailed information as to the fermentation process by which gellan gum is produced.

This observation, instead of supporting the reclassification of xanthan gum, strongly supports the needs for classification directives with regard to fermentation, and also points to the inadequacy of the available Technical Review and the need for a new one. Furthermore, it highlights the need for the reevaluation of gellan gum classification.

A subcommittee member mentioned a public comment citing a claim that xanthan gum had adverse health effects when used as a thickener in food for infants. At this point, the subcommittee's notes state: "*Upon further research of the references, it was noted that the cause may have been contamination of the product, and therefore was not a valid concern*."

As previously noted, several incidents occurred that were **not** due to contamination of the product, and that resulted in the death of several infants.[376] Moreover, the information provided to the subcommittee appears to have been *selectively* chosen to invalidate suggestions of adverse health effects associated with a product (Simply Thick) containing xanthan gum, and the voluntary recall in 2011 of the product in question. The belief at the time was that it potentially may have been contaminated with pathogenic bacteria.[377]

However, the **exclusive** use of this particular case is misleading. The same *Consumer Reports* article, referred to in the Handling Subcommittee notes, also references 2012 research that was done as a follow-up to the 2011 incident. The study reviewed 22 cases that resulted in several infant deaths involving Simply Thick, a xanthan gum–containing product, in terms of this product's associated risks to infants.[378] **There was no mention of potential bacterial contamination** of the product, and the ingestion of Simply Thick was linked to necrotizing enterocolitis. A third citation in the *Consumer Reports* study reported further on this story in 2013, linking Simply Thick to NEC in infants.[379] **The article also mentioned research examining three NEC cases in premature infants that were likely linked to xanthan gum**.[380]

But these documented health problems associated with xanthan gum were not presented for discussion to the Handling Subcommittee, according to the notes made available to the public.

The study of these readily available references, had they been mentioned during the Handling Subcommittee meeting, likely would have prompted additional research by the subcommittee, which then would have found the updated FDA press release[381] published in September 2012; in it the FDA warned parents, caregivers, and health care professionals that infants of any age may face increased risk of NEC if fed Simply Thick. **No**

[376] http://well.blogs.nytimes.com/2013/02/04/warning-too-late-for-some-babies/?_r=2
[377] http://www.fda.gov/NewsEvents/newsroom/PressAnnouncements/ucm256253.htm
[378] Beal J et al. 2012. Late onset necrotizing enterocolitis in infants following use of a xanthan gum-containing thickening agent. *Journal of Pediatrics* 161(2):354-6. doi: 10.1016/j.jpeds.2012.03.054
[379] http://well.blogs.nytimes.com/2013/02/04/warning-too-late-for-some-babies/?_r=0
[380] http://www.ncbi.nlm.nih.gov/pubmed?term=nec%20yang%20thickener
[381] http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm256250.htm

mention of "bacterial contamination" was made and the warning applied to all Simply Thick products, regardless of manufacturing provenance. Even though the FDA stated, "Further study is needed to determine if there is an actual link between consumption of Simply Thick and the development of NEC," the press release clearly warned against feeding Simply Thick to infants of any age.

The ingredients in Simply Thick are few: water, xanthan gum, sodium sulfate or citric acid, and potassium sorbate. **Xanthan gum is the primary ingredient besides water**.

Individual **lawsuits were filed** by parent whose infants died or suffered grave injuries linked to Simply Thick in 2011. The lawsuits alleged that Simply Thick, when fed to infants, caused necrotizing enterocolitis, a life-threatening condition. In 2014, the litigation was resolved on confidential terms.[382]

Xanthan gum is a known stimulant of the gut microbiome and can significantly increase the bacterial production of short-chain fatty acids (SCFA).[383] While this is a positive action in adults, as SCFA are vital to colon health, it can lead to the development of necrotizing enterocolitis in infants,[384] who are inherently very sensitive to SCFA.[385] Considering the probable link between xanthan gum and NEC, it would be a liability for the NOSB to relist it on §205.605(b).

At last, **the need for a limited scope TR was discussed** by the Handling Subcommittee, and even though it will not arrive in time for the Fall 2015 NOSB meeting, the **subcommittee will request one**. The subcommittee proceeded then with a vote on sunset and will work on a reclassification proposal separately, despite acknowledging the lack of key information necessary in making an informed decision.[386] Of note, after all this discussion, the subcommittee states that "*Xanthan gum satisfies all OFPA criteria*."

Vote:

Motion to remove Xanthan gum from §205.605(b)
Motion by: Zea Sonnabend
Seconded by: Harold Austin
Additional Discussion: none
Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0

CONCLUSION

The Cornucopia Institute **opposes the relisting of xanthan gum** under **§205.605(b)** Synthetics allowed because:

- Many of the substrates used in the production of xanthan gum may be of GMO origin;

[382] http://www.lieffcabraser.com/Personal-Injury/Infant-Child/Simply-Thick.shtml
[383] http://www.ncbi.nlm.nih.gov/pubmed/8329363
[384] http://well.blogs.nytimes.com/2013/02/04/warning-too-late-for-some-babies/?_r=0
[385] http://www.ncbi.nlm.nih.gov/pubmed/14962641
[386] Handling Subcommittee meeting notes, 06/02/2015

- Organic or natural agricultural substitutes exist; and
- The main use of xanthan gum is as a texturizer and stabilizer, uses that are not permitted by the organic regulations as stated in §205.600(b)(4).

Furthermore, Cornucopia **opposes** the reclassification of xanthan gum to **§205.605(a)** *Nonsynthetics allowed* or to **§205.606** *Nonorganic agricultural products,* and recommends that a new Technical Review be requested before moving to reclassify or renew this material on the National List.

PETITIONED MATERIALS

Lactates, Sodium and Potassium

SUMMARY

The Cornucopia Institute **cautiously supports the listing of sodium and potassium lactates** on the National List under §205.605(b) Synthetics allowed. However, it will be necessary to **add an annotation limiting their use to the inhibition of pathogens in meat products only and specifying that these substances be produced without the use of excluded methods**. This is necessary because these synthetic substances are commonly utilized as food additives to preserve meat and enhance flavor of meat, which is prohibited under §205.600(b)(4) preservative, color and flavor enhancement, and creation of texture.

Rationale:

- Sodium and potassium lactates are **synthetics**, manufactured by combining lactic acid with sodium or potassium hydroxides, both synthetics allowed under §205.605(b). [387]
- Many of the uses of these materials are prohibited by §205.600(b)(4)–preservative, flavor and color enhancement, and creation of texture—therefore the necessity to restrict its use to what is critically important: pathogen inhibition.
- A large percentage of the agricultural feedstock (corn or beet sugar) fermented to produce lactic acid may be **from GMO sources**, and the fermenting microorganisms may be genetically modified. Annotations prohibiting the use of fermentation microorganisms and feedstock produced without excluded methods are thus necessary.

DISCUSSION

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

On June 25, 2014, the NOP issued a memorandum to the NOSB regarding the regulatory statuses of sodium lactate and potassium lactate. In that memorandum, the NOP acknowledged that the interpretation published on January 22, 2004, was not consistent

[387] 2015 TR – Lactic acid and lactates. Page 3, lines 114-116

with previous NOSB recommendations on classification of materials, and they requested that the NOSB take up the petitions for these two substances for consideration for inclusion on the National List (McEvoy 2014)[388].

Sodium lactate and potassium lactate are **produced by reacting natural (fermented) lactic acid with sodium hydroxide, sodium carbonate or potassium hydroxide**, respectively. A reaction between an acid and a hydroxide is a synthetic reaction and the resulting compounds are **synthetics**. The literature does not suggest the existence of any non-synthetic forms of sodium lactate or potassium lactate. [389]

Sodium lactate and potassium lactate are often used to improve or enhance flavors and textures of food products, especially meat. However, they are mainly used in meat products (including cured meats) due to their anti-microbial activity. [390]

They were petitioned for use as a **pathogen inhibitor** in processed meat. Sodium and potassium lactates are some of the few anti-microbial compounds accepted by the FDA that can replace nitrates/nitrites in meat products and are GRAS.[391]

§205.600(b)(4) states: "*The substance's primary use is not as a preservative or to recreate or improve flavors, colors, textures, or nutritive value lost during processing, except where the replacement of nutrients is required by law*." This indicates very clearly that sodium and potassium lactate can only be used for the petitioned purpose as pathogen inhibitors in meat products.

Human and environmental health concerns

Lactate salts are GRAS, and pose **low potential risk to human health**. Their use in some applications can actually be beneficial to human health by reducing the risk of foodborne pathogens.[392]

Environmental hazards due to the manufacture or use of Lactic acid or its salts are considered low. However, the conventional fermentation-based process creates a surplus of calcium sulfate (gypsum) waste, the disposal of which can be problematic. Some of the current commercial uses for gypsum are in the manufacture of plasterboards and as a soil amendment, for which it is marketed by some of the manufacturers of lactic acid. Other lactic acid production processes are currently being investigated to enhance efficiency and productivity while diminishing waste production. [393]

[388] McEvoy, M. "USDA Agricultural Marketing Service." *National Organic Program.* January 25, 2014. http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5108095
[389] 2015 TR – Lactic acid and lactates. Page 13, lines 611-615
[390] Ibid. Page 14, lines 670-671
[391] Ibid. Page 5, lines 171-179
[392] Ibid. Page 17, lines 848-850
[393] Ibid. Page 16-17, lines 770-805

Essentiality and alternatives

Sodium lactate and potassium lactate are mainly used as preservatives in meat products (including cured meats) for food safety reasons as they are important factors in the control of *Lysteria monocytogenes, Clostridium botulinum, Salmonella, E. coli O157:H7* and other microorganisms[394] responsible for food-borne illness. Nitrates and nitrites are other preservatives commonly used in nonorganic cured meats mainly for the control of *Clostridium botulinum* and to assist in the control of *Listeria monocytogenes* but are not allowed in organic products.

However, **there are a variety of allowed natural products and organic products that could be used instead of lactates**. These include various organic acids, listed under 205.605(a), bacteriophages (listed under microorganisms) which are utilized as an antimicrobial to control bacteria during food processing. And there are also some lactic acid cultures that have the ability to reduce naturally-occurring nitrates to nitrites and have been used for over 100 years to cure meat, especially dry sausage. These cultures are used together with celery juice powder, a pseudo-natural source of nitrate to effectively control *Clostridium botulinum* and *Listeria monocytogenes*. Celery powder is available in organic form, although nitrate levels are typically lower in organic celery powder. [395] Vinegar powder as well as other fruits powders (lime, lemon, cranberry, and cherry) and essential oils are all agricultural products available in organic forms that can be effective antimicrobials and are being actively investigated. [396]

Handling Subcommittee discussion and vote

The history and the use of sodium and potassium lactate was reviewed, and it was noted that the original petitioned use for these materials was in Ready-to-Eat meat and poultry products as a pathogen inhibitor, especially for use in controlling *Listeria monocytogenes*.

The subcommittee noted that it is stated in the 2015 Technical Report (compiled by OMRI) 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).

And finally, the Handling Subcommittee is requesting from the appropriate organic stakeholders and/or certifiers for additional information that would assist the NOSB in its consideration of these two petitioned materials. In particular it would like information specific to the manner these two materials are being utilized and whether these materials are currently being used in ways other than the original petitioned use. The Handling Subcommittee is wondering which one (between sodium lactate and potassium lactate) is more commonly used.

[394] 2015 TR – Lactic acid and lactates. Page 17, lines 848-850
[395] Ibid. Page 18-21, lines 901-1032
[396] Ibid. Page 21-24, lines 1041-1197

Classification Motion:
Motion to classify both Sodium Lactate and Potassium Lactate as synthetic.
Motion by: Harold Austin
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 Austin
Seconded by: Ashley Swaffar Yes: 4 No: 1 Abstain: 2 Absent: 0 Recuse: 0

CONCLUSION

The Cornucopia Institute **cautiously supports the listing of sodium and potassium lactates** on the National List under §205.605(b) Synthetics allowed. However, there are many alternatives to these substances, some natural and some organic agricultural as listed in the TR[397]; therefore these alternatives should be carefully considered by the NOSB when evaluating the listing of sodium and potassium lactates on the National List under §205.605(b) Synthetics allowed.

In addition, these compounds are used specifically for flavor enhancement and the preservation of meat,[398] which is prohibited under §205.600(b)(4)–preservative, color and flavor enhancement, and creation of texture. If they were to be listed under §205.605(b), then their use should be in compliance with §205.600(b)(4) and restricted to the petitioned use as pathogens inhibitors by annotation.

[397] 2015 TR – Lactic acid and lactates. Page 21-24, lines 1041-1197
[398] Ibid. Page 15, lines 720-732

LIVESTOCK SUBCOMMITTEE

2017 SUNSET MATERIALS

Aspirin

SUMMARY

The Cornucopia Institute **supports** the relisting of aspirin of on the National List under §205.603 synthetic substances allowed for use in organic livestock production.

Rationale:

- Aspirin is an effective analgesic used to reduce pain and fever in livestock.
- Aspirin is widely available and one of the safest pain relieving drugs.
- When properly used there is very little concern with residues in meat and dairy products.

DISCUSSION

The synthetic drug aspirin is the most widely used, commonly available pain relieving drug on the market today for livestock. It is very inexpensive and available without a prescription from a veterinarian. Because toxicity is of little concern, withholding periods are short—the FDA recommends, but does not mandate, 24 hours.

Another benefit of aspirin use is its ease of administration because it can be given orally in bolus or tablet form, or dissolved in drinking water when treating a group of sick animals. Pig producers can provide aspirin in drinking water to help reduce fever in groups of pigs, allowing the pigs to feel better and get back on feed sooner, which helps boost recovery. By administering aspirin via the animals' water, a producer can quickly and easily treat a group of pigs without causing the additional stress generated by the individual handling that is necessary when administering other medications. Aspirin can effectively reduce diarrhea in piglets, which enhances their survival and growth rate.[399]

However, there are some negative aspects to aspirin use. First, it is not nearly as effective in ruminant animals as it is in monogastric animals such as horses and pigs, because the higher pH in the rumen dramatically slows absorption.[400, 401] For that reason, the drug Flunixin has become the main nonsteroidal anti-inflammatory drug (NSAID) for cattle,

[399] Xu, Z.R., Kornegay, E.T., Sweet, L.A., Lindemann, M.D., Veit, H.P. and Watkins, B.A. Effects of feeding aspirin and soybean oil to weanling pigs. J. Anim. Sci. 68, 1639, 1990.
[400] Gingerich, D.A, Baggot, J.D. and Yeary, R.A., Pharmacokinetics and dosage of aspirin in cattle. J. Am. Vet. Med. Assoc. 167, 945, 1975.
[401] Wren, Jenny. Options for Pain Management. Bovine Veterinarian. January 2008.

sheep, and goats. Second, aspirin can interfere with blood clotting, and as a COX 1 inhibitor it can cause gastrointestinal problems if overused.

International regulations

IFOAM Basic Standards prohibits the use of synthetic drugs with the following exceptions:

> *Natural and alternative medicines and treatments are unlikely to be effective to cure sickness or injury, or are not available to the operator, and*
> *The chemical allopathic veterinary drugs or antibiotics are used under the supervision of a veterinarian, and*
> *Withdrawal periods shall be not less than double of that required by legislation, or a minimum of 14 days, whichever is longer.*

Human health concerns

The only residue concerns are that aspirin can cause Reye's syndrome in children. However, considering that aspirin is quickly metabolized, the FDA recommends only a 24-hour withholding period for meat and dairy production.

Environmental concerns

There do not appear to be any environmental concerns with proper use of aspirin.

Technical Report

The TAP review from 1994 is woefully inadequate and needs to be updated. The review includes a short one-page checklist filled out by two reviewers, both veterinarians: Dr. Marta Engel and Dr. William Zimmer. While both veterinarians are familiar with holistic animal care, and there is no conflict of interest, there is not enough information provided for the NOSB to make an informed decision. There should be information in the review on how the product is produced, how it is used, its efficacy, and its safety.

Essentiality; alternatives that exist

There are herbal and homeopathic remedies available to treat pain and fever in livestock. Arnica montana is a common ingredient in herbal and homeopathic remedies for treating pain. For instance, numerous studies indicate that herbal and homeopathic remedies made from arnica can reduce pain and swelling as well as improve healing.[402] However, these studies have not been done in livestock. Studies done in humans have demonstrated that developing the correct dosage is essential for both effectiveness and to minimize side effects.[403]

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[402] http://klemow.wilkes.edu/Arnica.html

[403] Iannitti T, et al. Effectiveness and Safety of Arnica montana in Post-Surgical Setting, Pain, and Inflammation. Am J Ther. 2014 Sep 17. [Epub ahead of print]

The herbs feverfew and white willow bark may reduce fever but may not reduce inflammation. Some holistic vets recommend aloe in the form of pellets or liquid to help reduce fever and inflammation as well. They may also recommend homeopathic remedies including belladonna, pyrogen, and aconite.

It may be difficult for livestock producers to develop effective dosage levels with arnica or other herbal treatments, especially since there are few veterinarians who have experience with holistic medicine. However, there are books available written by holistic veterinarians that can help livestock producers develop appropriate doses of herbal remedies.

Additionally, holistic veterinarians often prescribe a regimen of treatments to help an animal through times of illness, pain, or stress. The theory is that the animal needs support in a variety of ways to help overcome their ailment. The objective is to bring the animal back to health rather than just treating a symptom and ignoring the underlying cause.

Livestock Subcommittee action

The Livestock Subcommittee concluded that aspirin has been evaluated against the OFPA criteria and was found to satisfy all of them. There was no request for an updated TR.

The subcommittee motion to remove aspirin from §205.603 as a treatment for livestock was Yes: 0 No: 6 Abstain: 0 Absent: 2 Recuse: 0

CONCLUSION

Cornucopia institute **recommends** the relisting of aspirin on the National List under §205.603 synthetic substances allowed for use in organic livestock production. Aspirin is a relatively safe, widely available, and low-cost pain reliever for livestock. In following the historic safe harbor philosophy of organics, the NOSB would be well served to craft **an annotation requiring the 24-hour withholding period** that the FDA recommends.

Butorphanol – 2017 Sunset

SUMMARY

The Cornucopia Institute **supports** the relisting of butorphanol on the National List under §205.603 Synthetic substances allowed for use in organic livestock production.

Rationale:

- It is an effective analgesic used to reduce pain during veterinary surgical procedures.
- It reduces risk to livestock handlers during surgery, because the animal is sedated.
- The potential toxicity to humans, animals, and the environment is minimal when used appropriately.
- Non-synthetic alternatives are not as effective or as safe.

DISCUSSION

Butorphanol is a synthetically derived opiate used in both human and veterinary medicine to help reduce pain. Opiates are narcotic analgesics that can directly suppress the central nervous system. There are both naturally derived and synthetically derived opiates, which are collectively known as opioids. Natural opiates are extracted directly from the dried milk of the opium poppy, whereas synthetic opiates are synthesized from natural opiates. Humans and other animals have proteins called *opioid receptors* located in the brain, spinal cord, and gastrointestinal tract. Opioids work by attaching to these receptors and blocking the transmission of pain signals to the brain.[404]

On the market since 1979, butorphanol has several decades of use and is considered one of the safest opioids available. Derived from morphine, which is also used as an analgesic, butorphanol works more rapidly for pain relief. Additionally, it is much less addictive than morphine making it less of a liability for drug abuse than morphine.[405] However, as with all opiates there is the possibility of users becoming dependent on the drug. Thus, it is controlled and available for use only under the guidance of a veterinarian or by prescription from a physician.

Butorphanol was part of a group of synthetic drugs recommended for approval for livestock use by the NOSB in 2002, and finally added to the Federal Register in December of 2007. Organic farmers petitioned the use of butorphanol to treat cattle prior to surgery in order to reduce pain associated with that surgery.[406] With pain reduced to manageable levels, cattle can tolerate surgery and recover more quickly.

When used appropriately and administered by a veterinarian or under a veterinarian's guidance, and proper withdrawal periods are followed, there will be no harm to humans

[404] http://www.isate.memphis.edu/opiate.html
[405] NOSB 2002 TAP Review
[406] http://www.foodconsumer.org/777/8/USDA_may_allow_drugs_and_additives_for_organic_livestock.shtml

who consume the meat and milk from treated animals.[3] Withdrawal periods of 42 days for meat animals and 8 days for dairy are double that of conventional livestock treated with the same drug.[407]

Torbugesic® is the trade name of an injectable form of butorphanol, called butorphanol tartrate solution. It is administered intravenously and reaches peak active analgesic effect in 15 to 30 minutes, with a duration of up to 1 hour in cattle. The compound acts as an agonist at kappa-opioid receptors and mixed agonist-antagonist at mu-opioid receptors in the central nervous system to alter the perception of pain.[408]

A version for humans, known as Stadol®, is also used for treating severe chronic headaches, for pain management for surgery, or as a preoperative medication for pain during labor. [6] Drugs administered during labor raise concerns for safety and butorphanol is no exception; it has been tested extensively to determine negative effects on the fetus.[409]

Tests show that the drug is metabolized within hours in the body by the liver and excreted in the urine and eventually eliminated in the feces.[3]

International regulations

IFOAM Basic Standards:
5.7.1.
The well-being of the animals is the primary consideration in the choice of illness treatment. The use of conventional veterinary medicines is allowed when no other justifiable alternative is available.

5.7.2.
Where conventional veterinary medicines are used, the withholding period shall be at least double the legal period.

Butorphanol is permitted for use in veterinary medicine for organic livestock production in the European Union.

Canadian Standards do not mention butorphanol specifically, but allow for the use of local anesthetics and require a withdrawal period of 90 days after administering to livestock intended for slaughter, and 7 days after administering to dairy animals. Preference is given to natural alternatives.

Human health concerns

Due to the long withholding periods of 42 days for meat animals and 8 days for dairy animals it is not likely that there are detrimental amounts of butorphanol or its metabolites

[407] https://www.avma.org/News/JAVMANews/Pages/080215b.aspx
[408] http://www.who.int/medicines/areas/quality_safety/4.1ButhorphanolCritReview.pdf
[409] JNMA J Nepal Med Assoc. 2008 Apr-Jun;47(170):57-61. The efficacy and safety of low dose epidural butorphanol on postoperative analgesia following cesarean delivery.

in the meat and milk from treated animals. The USDA noted that it did not use food safety arguments to support doubling the withdrawal periods compared to conventional production use, but rather the department decided that longer withholding periods would be more in line with consumer expectations for organic livestock production.

Environmental concerns

There do not appear to be any environmental concerns with proper use of butorphanol. The dosage amount used in a single animal is very small and breaks down within hours. The residue metabolites of the drug that are excreted by the animal are water soluble and are not likely to accumulate in the environment. Additionally, the metabolite residues are inert and not considered a safety concern.

Essentiality; alternatives that exist

While there are non-synthetic opiates available, such as morphine, there are several reasons why butorphanol is preferred. Adverse side effects on the animal are lessened and the substance is much less addictive and is therefore less likely to be diverted to illicit use.

Although it is a synthetically derived drug, butorphanol is a powerful and useful tool for managing and mitigating pain during surgery. Welfare of the animal must be of primary concern during surgical procedures, which require the use of anesthesia to alleviate pain. Butorphanol is a safe and effective anesthesia when used properly.

Livestock Subcommittee action

July 7, 2015: The lead, subcommittee member Colehour Bondera, summarized the material, its use, and the public comment received for the first posting. Members made some minor modifications and proceeded to a vote. The vote to remove butorphanol from §205.603 was Yes: 0, No: 6

CONCLUSION

The Cornucopia Institute **supports the relisting of butorphanol** on the National List under §205.603 Synthetic substances allowed for use in organic livestock production. The Cornucopia institute supported the wishes of organic livestock producers who had the welfare of their animals in mind when they first petitioned the NOP to allow for the use of butorphanol over a decade ago. Since that time there have been no new alternative natural or synthetic drugs developed that are as equally safe and effective as butorphanol.

Chlorhexidine – 2017 Sunset

SUMMARY

The Cornucopia Institute **supports the relisting of chlorhexidine** at §205.603(a) as a restricted medical treatment allowed for surgical procedures conducted by a licensed veterinarian. Its use as a teat dip under the general supervision of a licensed veterinarian can be justified and recommended in the presence of blood and discharges when alternative germicidal agents and/or physical barriers have lost their effectiveness. Withholding period shall be at least double the legal period as per the FDA required labeling. Chlorhexidine should continue to be restricted as listed above**.**

Rationale:

- Chlorhexidine is a rapidly acting, non-irritating germicide composed of biguanide compounds.
- Chlorhexidine provides an effective alternative to iodine and iodophor teat dip products when there are bacteria resistant to those products.

DISCUSSION

Chlorhexidine is a rapidly acting, non-irritating germicide composed of biguanide compounds. This germicide acts by precipitating cytoplasmic proteins and macromolecules, and is effective against most Gram-positive and -negative bacteria as well as some viruses. However, under high microbial contamination conditions, some pathogens, such as *Serratia* and *Pseudomonas* species, can survive in chlorhexidine-based products and may become potential mastitis pathogens.[410] Chlorhexidine has both bacteriostatic (inhibits bacterial growth) and bactericidal (kills bacteria) mechanisms of action, depending on its concentration.

Efficacy

Chlorhexidine use is restricted in organic livestock production and may only be used under veterinary supervision. As a teat dip, it is a last resort germicide used when other substances have lost their effectiveness or a specific pathogen becomes problematic. This material does appear to have some advantages over the typically used iodophor substances. It is fast acting and, when applied post-milking, continues to kill pathogens for another five to six hours. It is non-irrigating to the skin of the teat, an important factor in the prevention of new mastitis cases. It exhibits higher killing efficacy against *Staph aureus*, the most common mastitis-causing pathogen worldwide, than iodophors. Under circumstances where iodophors fail to control this pathogen, chlorhexidine can be an effective alternative.

[410] Nickerson, Stephen C. (2001). Choosing the Best Teat Dip for Mastitis Control and Milk Quality. *NMC-PDPW Milk Quality Conference* Proceedings. April, 2001.

Its disadvantages are that it is more toxic to produce than many of the other approved antimicrobials, it can be expensive to purchase, and it requires veterinary supervision.

There are an increasing number of prevalent studies that report reduced levels of pathogen susceptibility to chlorhexidine used for human medical uses, with emphasis on the susceptibility of MRSA (a form of Staph). Clinical use of chlorhexidine is likely to continue to increase, which may lead to the emergence of new pathogen strains with reduced susceptibility. Indiscriminate chlorhexidine use in the absence of efficacy data should be discouraged.[411] This might be a good reason to limit its use in organic dairy production; however, similar antimicrobial resistance research on chlorhexidine applications in livestock does not appear in the literature.

Livestock Subcommittee action

On June 16, 2015, both the lead and the subcommittee chair summarized the material. Public comment was mixed and the subcommittee received no answers to the question about use.

Vote to remove chlorhexidine from §205.603(a) was Yes: 0, No: 6

CONCLUSION

The Cornucopia Institute **supports the relisting of chlorhexidine on §205.603(a)** but only if its restricted-use status remains intact.

[411] Horner C., D. Mawer, and M. Wilcox. (2012). Reduced susceptibility to chlorhexidine in staphylococci: is it increasing and does it matter? *Journal of Antimicrobial Chemotherapy. July 24, 2012: 1-13.*

Ethanol/Isopropanol – 2017 Sunset

SUMMARY

The Cornucopia Institute **supports the relisting of ethanol** at §205.603(a) for its current livestock uses. However, we recommend that **isopropanol sunset** as there are questions about the environmental effects of its manufacturing and it is not approved for topical use; therefore, it has limited essentiality.

The National Organic Program final rule currently allows the use of ethanol in organic livestock production as a disinfectant and sanitizer for surface and topical use only. The substance is prohibited for use as a feed additive in organic production.

The final rule also allows the use of isopropanol in organic livestock production as a surface disinfectant only. It is not approved for topical use on livestock, such as in eyewashes or teat dips. To clarify, **ethanol can be used topically and isopropanol cannot**.

DISCUSSION

Ethanol (also known as "ethyl alcohol") is a volatile, flammable, colorless alcohol with the molecular formula of CH_3CH_2OH. Isopropanol (also known as "rubbing alcohol") is also a volatile, flammable, colorless alcohol with the molecular formula $(CH_3)_2CHOH$.

Organic livestock producers may use alcohols (i.e., ethanol and isopropanol) for sanitizing and disinfecting surfaces (e.g., production implements, troughs, and floor drains) and ethanol during medical treatments as a topical disinfectant.[412],[413] Indeed, a protocol for the disinfection of methicillin-resistant *Staphylococcus aureus* (MRSA) on sows and their piglets using alcohol solutions was recently reported in the literature.[414] Rubbing alcohol is also used to disinfect production implements such as livestock tagging applicators. Alcohols, such as ethanol and isopropanol, provide rapid broad-spectrum antimicrobial activity against vegetative bacteria, viruses, and fungi but lack activity against bacterial spores.[415]

[412] Jacob J. 2013. Cleaning and Disinfecting in Organic Poultry Production. E-extension. Retrieved March 4, 2015 from http://www.extension.org/pages/67937/cleaning-and-disinfecting-in-organic-poultry-production#.Up96fWRDvzh.

[413] Dvorak G. 2008. Disinfection 101. Center for Food Security and Public Health. Iowa State University. Retrieved March 4, 2015 from: http://www.cfsph.iastate.edu/Disinfection/Assets/Disinfection101.pdf.

[414] Pletinckx LJ, Dewulf J, Bleecker Y De, Rasschaert G, Goddeeris BM, Man I De. (2013). Effect of a disinfection strategy on the methicillin-resistant Staphylococcus aureus CC398 prevalence of sows, their piglets and the barn environment. *Journal of Applied Microbiology* 114:1634–1641.

[415] McDonnell G, Russell AD. (1999). Antiseptics and disinfectants: activity, action, and resistance. *Clinical Microbiology Reviews* 12:147–179.

Human health concerns

According to the U.S. EPA, ethanol is practically non-toxic (Category IV) based on acute oral and inhalation toxicity tests as well as primary eye and dermal irritation studies. Isopropanol is slightly toxic (Category (III) to practically non-toxic (Category IV) based on similar EPA studies.[416]

Environmental health

Commercial methods for the industrial production of ethanol include chemical synthesis from ethylene or the fermentation of sugars, starch, or other biomass using either yeast or genetically modified bacterial strains. As of 2001, fermentation accounted for 90% of the ethanol production in the U.S., Western Europe, and Japan.[417] Considering the continued advancements in fermentation-based technologies and increasing global demands for fuel ethanol, this figure was closer to 95% in 2013.[418]

Although ethanol is a volatile organic compound and potentially contributes to the formation of ozone and photochemical smog, large-scale releases of ethanol under normal uses in organic livestock production are unlikely. Volatilization and biodegradation are also primary mechanisms for removal of ethanol from water. According to the TR, line 557, ethanol is practically non-toxic to slightly toxic to freshwater and marine invertebrates.

Isopropanol, on the other hand, is almost entirely produced by chemical synthesis. Specifically, indirect and direct methods for the hydration of petroleum-derived propylene are the primary commercial processes for the production of isopropanol. A variety of methods are also available for the fermentative production of isopropanol from carbon sources, such as starch, sugar, and cellulose, using genetically engineered yeast and bacteria.[419] However, most of these biological fermentation methods are limited to laboratory scale production levels and are geared toward production of isopropanol as a biofuel. This means that commercial isopropanol products are made via intense chemical processes likely to have some environmental health impacts. The TR did not discuss in depth the potential environmental impacts from the manufacture of synthetic isopropanol.

Efficacy

Ethanol is considered virucidal; isopropanol is not effective against non-enveloped viruses. An important consideration with alcohols is the concentration used, with 70% to 90%

[416] U.S. EPA. 1995. Reregistration Eligibility Decision (RED): Aliphatic Alcohols. US Environmental Protection Agency.
[417] Logsdon JE. 2004. Ethanol. Kirk-Othmer Encyclopedia of Chemical Technology
[418] Berg C. (2013). World Fuel Ethanol: Analysis and Outlook. Prepared for the Japanese Ministry of Economy, Trade and Industry (METI).
[419] Papa AJ. 2011. Propanols. Ullman's Encyclopedia of Industrial Chemistry.

being optimal. Higher concentrations (95%) are actually less effective because some degree of water is required for efficacy (to denature proteins). Alcohols evaporate quickly leaving no residue. The efficacy of alcohols is reduced by the presence of organic matter. Alcohols are highly flammable, can cause damage to rubber and plastic, and can be very irritating to injured skin.[420]

Ethanol-based topical antiseptics may include low levels of other biocides (e.g., chlorhexidine), which remain on the skin following ethanol evaporation, or excipients, which extend the life span of ethanol on skin and thus increase product efficacy.[421]

As a teat dip, alcohols are relatively affordable and readily available, and have low human (and presumably livestock) toxicity. However, as previously mentioned, they are ineffective against bacterial spores[422] and will dry out teats unless emollients are used. Isopropanol is currently not approved for livestock topical use (which means it can't be used as an active ingredient in a teat dip).

Livestock Subcommittee action

On June 16, 2015, the lead summarized the material and noted that for the review he used the previous TAP review, public comments, and NOSB recommendations. Isopropanol is widely used and needed. Public commenters were supportive of relisting.

The vote to remove isopropanol from §205.603 was Yes: 0 No: 6

CONCLUSION

The Cornucopia Institute recommends **relisting ethanol on the National List at §205.603(a)** for its current livestock uses. Ethanol is of low toxicity and is an effective germicide and disinfectant with a wide range of uses. However, we would like to see an annotation (not currently allowed under the NOP sunset procedures, unilaterally implemented) whereby **the only source of ethanol is from biological fermentation**.

Since isopropanol is not commercially produced using biological fermentation practices, we **recommend that isopropanol sunset**. The chemical synthesis of isopropanol generates toxic byproducts and does not likely meet the OFPA environmental criteria. Ethanol (generated from fermentation) can be used in its place. Given that its uses are limited according to its current listing (no topical use), it should be relatively easy for producers to utilize an alternative material, such as ethanol, hydrogen peroxide, iodophors, etc., as a replacement.

[420] Dvorak G. 2008. Disinfection 101. Center for Food Security and Public Health. Iowa State University. Retrieved March 4, 2015 from: http://www.cfsph.iastate.edu/Disinfection/Assets/Disinfection101.pdf.
[421] McDonnell G, Russell AD. (1999). Antiseptics and disinfectants: activity, action, and resistance. *Clinical Microbiology Reviews* 12: 147–179.
[422] CDC 2008

Flunixin – 2017 Sunset

SUMMARY

The Cornucopia Institute cautiously **supports** the relisting of flunixin on the National List under §205.603 synthetic substances allowed for use in organic livestock production.

Rationale:

- Flunixin is a nonsteroidal anti-inflammatory drug (NSAID) that effectively reduces pain, inflammation, and fever in livestock.
- Flunixin is required by the FDA to be administered by IV only, because when injected it often creates lesions with residues of the drug; it cannot be administered orally because of gastrointestinal side effects.
- Flunixin residues in meat are harmful to humans and lethal to birds of prey, should they feed on a carcass.
- The NOSB should consider the NSAID meloxicam as a possible substitute for flunixin, because it is much safer to use, and less likely to leave dangerous residues in the meat.

DISCUSSION

The main concern of organic livestock producers is the care and welfare of their livestock; therefore, they want to be able to utilize the most effective, practical tools—including medications and drugs that are synthetically derived—available to them for the care of their livestock. The NSAID flunixin is one of those tools; it is an important synthetic drug for relieving pain, and reducing inflammation and fever in livestock when they are ill or injured. As such, The Cornucopia Institute supports the continued use of flunixin in organic livestock production.

Flunixin is the primary drug recommended by veterinarians for most situations in which livestock suffer from severe inflammation and fever, such as pneumonia. Within 1 to 2 hours the drug can bring significant relief to the animal allowing it to start eating sooner, a critical step in helping animals recover. A single dose can often remain effective for up to 30 hours. Additionally, one study showed that its use in animals with respiratory infections can help reduce damage to their lungs.[423]

It is important to note that flunixin treats symptoms only and not the underlying cause of those symptoms. While it can temporarily bring relief to an animal, which can help recovery, it can also mask the illness or injury. It is not a substitute for actual treatment of the root cause of the symptoms.

[423] Clinical Efficacy of Flunixin Meglumine Compared with Other NSAIDS
http://www.banamine.com/research/ClinicalEfficacy.asp

Also, like most NSAIDs, flunixin can cause gastrointestinal side effects if overused. In fact, in order to avoid these side effects the only FDA-approved method of administration is through IV, which prevents carcass lesions caused by intermuscular injection. Those lesions can be another source of pain and stress for the animal and reduce the meat yield and quality.

An issue arising from the requirement for IV administration is that, due to the extra time and skill needed to properly IV a drug, most livestock producers instead directly inject flunixin.

Human health and environmental concerns

Improper use of flunixin results in drug residues in the meat which are toxic to humans and to some animals, such as birds of prey. Flunixin residues in meat can cause kidney problems in humans and kills birds consuming the contaminated meat or carcass. Livestock producers will often ship animals to slaughter within days following treatment, when the animals are showing signs of recovery, in order to salvage some sort of value from that animal. While this practice violates withholding requirements and is illegal, it is still too common. In fact, **residues from flunixin are one of the top three drug residues commonly detected in USDA inspected meat plants**.[424]

Flunixin residues appear to be problematic only when cattle are treated with flunixin subcutaneously or with an intramuscular injection. However, when cattle are properly treated with flunixin using approved intravenous injection, residues of flunixin are eliminated from the system within 48 hours.[425]

An additional issue with flunixin residues in carcasses results from the improper disposal of animals that were treated but died. If birds of prey such as vultures, hawks, and eagles consume meat from those carcasses, flunixin residues are toxic enough to kill them.[426] It is essential that livestock producers properly dispose of treated livestock mortalities. Animals need to be incinerated, buried, or composted in order to prevent scavenging.

International regulations

IFOAM Basic Standards do not allow for the use of flunixin in livestock production nor do Canadian Organic Standards. However, flunixin is allowed in organic livestock production in New Zealand.

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[424] Don't Let Drug Residues in Meat Damage Your Dairy's Reputation. http://www.agrilabs.com/t-BHW_Dairy_Fall2011_DrugResiduesInMeat.aspx

[425] Kissell, L.W. Plasma pharmacokinetics and milk residues of flunixin and 5-hydroxy flunixin following different routes of administration in dairy cattle. Journal of Dairy Science, Volume 95, Issue 12, 7151-7157

[426] Zorrilla, I., Martinez, R., Taggart, M. A. & Richards, N. *Conserv. Biol.*http://dx.doi.org/10.1111/cobi.12417 (2014).

Essentiality; alternatives that exist

The Cornucopia Institute recommends, as an alternative, that the Livestock Subcommittee evaluate the NSAID **meloxicam** for use in organic livestock production, because it is safer to administer (orally instead of by IV) and longer acting, and the residues are not lethal to birds consuming meat from the carcasses of treated animals.

However, another very common NSAID for use in livestock production, **aspirin**, is already on the National List. Aspirin is an inexpensive, readily available over-the-counter drug for treating pain and inflammation. It is relatively quickly metabolized and the residues are not considered toxic. However, the FDA recommends a 24-hour withholding period which Cornucopia feels should be adopted, through an annotation, as a restricted-for-use in organically managed cattle. However, there has not been enough research to establish effective treatment levels when using aspirin. Also, the available research on the use of aspirin as a treatment in cattle seems to indicate that it may not be effective or long-lasting for reducing pain.[427]

Livestock Subcommittee action

August 18, 2015: The subcommittee motion to remove flunixin from §205.603 as a treatment for livestock was Yes: 0 No: 4 Abstain: 1 Absent: 1 Recuse: 0

CONCLUSION

The Cornucopia Institute cautiously supports the relisting of flunixin (flunixin meglumine) on the National List under §205.603 Synthetic substances allowed for use in organic livestock production. However, emphasis should be made on the importance of administering this product according to FDA regulations, and to follow the required withholding periods in order to eliminate contamination from residues in the meat from the treated animals.

As with other synthetic pharmaceuticals used in organics, the community might be well served to see an annotation added that would increase the withholding period, adding a margin of safety, over and above what is required for use in conventional livestock management.

[427] Wren, Jenny. Options for Pain Management. Bovine Veterinarian. January 2008.

Formic Acid – 2017 Sunset

SUMMARY

The Cornucopia Institute **recommends the relisting of formic acid** on the National List under §205.603 Synthetic substances allowed for use in organic livestock production. However, an **annotation should be added only to restrict the use of formic acid to prepared formic acid pads**, which are significantly less hazardous to human health than concentrated formic acid.

Rationale:

- Formic acid is a parasiticide that can be used to effectively treat varroa and tracheal mite infestations in bee hives.
- Unlike other synthetic treatments, mites have not developed resistance to formic acid even after decades of use.
- Formic acid can do some harm to bee colonies.
- Concentrated formic acid is quite harmful to humans, and beekeepers should use prepared formic acid pads which are readily available and much safer to use.
- Natural alternatives are not safer to use and may be less effective.
- The most effective, safest, longest-term solution to parasitism by varroa and tracheal mites is to encourage the development of resistance in honey bee populations.

DISCUSSION

Synthetically derived formic acid is an EPA-approved fumigant that is used as a parasiticide to treat and control varroa and tracheal mite infestations in bee hives. Mites were first detected in the U.S. in the early 1980s and are now known to play a major and often devastating role in colony losses across the country.[428]

Formic acid treatment is one of the few chemical approaches that effectively controls varroa and tracheal mites with no reports of resistance development to the chemical. In addition, it is relatively inexpensive. It is imperative for the organic beekeeping industry to be provided with the tools needed to maintain strong and healthy bee colonies. Formic acid is a relatively effective tool for that purpose. However, as described below, it is not a sustainable long-term approach to maintain healthy honey bee populations.

The most common formic acid treatment is done by using pads treated with formic acid which are positioned in the hives before honey production begins. The slow release of formic acid fumes kills both tracheal and varroa mites, while generally leaving the bees

[428] http://www.clemson.edu/extension/beekeepers/factsheets/honey_bee_tracheal_mite.html

unaffected, although it may kill some bees or stop egg laying, especially in weaker colonies during hot weather.[429]

Formic acid is a naturally occurring compound in some fruits and nectar, and in honey. It is also the chemical responsible for bites and stings in stinging nettles, bees, and ants. However, **there are no natural sources of formic acid currently available commercially** for use in organic agriculture, and all forms of the chemical are synthetic byproducts obtained from the manufacturing of other chemicals such as acetic acid.

Formic acid in its concentrated form is quite caustic to humans and dangerous if inhaled, ingested, or contacted with skin. It should be used with a respirator, required by EPA regulations. There are safer formic acid products, such as Miteguard II and Mitegone, that package the acid in pads that can be placed in the hive. These pads slowly release formic acid fumes into the hive.

The main issue with formic acid is not that it is synthetic or potentially harmful to bees and beekeepers—after all, alternative natural products currently approved for organic beekeeping, such as wintergreen and thymol, can be just as harmful. Instead, the real problem is summed up well by Massachusetts state bee-inspector Anita Deeley: "When beekeepers rely on treatments for pests, you end up breeding stronger pests and diseases that are resistant to treatments, instead of breeding better bees resistant to pests and diseases."[430] It is likely that mites will eventually develop resistance to formic acid, as they have to most other chemical treatments.

There is good scientific evidence, along with plenty of anecdotal evidence from commercial beekeepers, that breeding mite-resistant honey bees effectively lowers the rate of infection to sustainable levels, and does not lower production compared to non-resistant bees that are instead treated for mite infestation.[431]

"Russian bees," for instance, are effectively being used to breed mite resistance into U.S. bee genetics, without loss of production and without the dangerous temperament of African bees. Russian bees also have multiple ways to protect themselves from mite infestation, such as grooming and hygienic behaviors. Additionally, they demonstrate resistance to diseases as well.[432]

Admittedly, it takes time to develop mite-resistant strains of bees; during this period it is appropriate to use formic acid to help keep beekeeping profitable until stable resistant honey bee strains are developed that no longer need treatments. Randy Oliver, a beekeeper and the author of *Scientific Beekeeping*, explains his experience, which is likely similar to many beekeepers who have followed a similar approach:

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[429] http://scientificbeekeeping.com/the-learning-curve-part-3-the-natural-miticides/
[430] http://www.beverlybees.com/treatment-free-beekeeping-what-is-it/
[431] Spivak and Reuter. 2001. Varroa destructor infestation in Untreated Honeybee Colonies Selected for Hygienic Behavior. J. Econ. Entomo. 94(2): 326-331
[432]http://scientificbeekeeping.com/choosing-your-troops-breeding-mite-fighting-bees

> My first step in getting the upper hand on the mite was to forswear the coddling of wimpy bees with synthetic chemicals. This decision cost me dearly as colonies collapsed right and left. But thanks to the genetics of selected mite-resistant queens, my colonies now look better than they have in many years, and every box is again full of healthy bees.[433]

International regulations

The European Economic Council Regulation allows the use of formic acid to protect bee hives.

Canadian organic standards allow the use of formic acid only after honey has been harvested for the season and up to 30 days before the addition of trays to collect honey for the upcoming season.

Environmental concerns

There do not appear to be any environmental concerns with appropriate handling and utilization of formic acid. The amounts used are relatively small. Low levels of formic acid ubiquitous in the environment are not considered harmful.

Human health concerns

Formic acid in its concentrated form can be quite hazardous to humans. While pretreated formic acid pads are relatively safe to handle and use, they are considerably more expensive than purchasing concentrated formic acid and making your own pads, so many beekeepers prefer to do the latter. The concentrated acid can severely irritate and damage skin, eyes, and mucous membranes, and is toxic to kidneys. The fumes can irritate and damage lungs and can cause respiratory distress leading to death.[434] Such hazardous chemicals should not be allowed for use in organic agriculture. For this reason, the NOSB should provide an annotation limiting formic acid use to prepared formic acid pads, which are much safer to use.

Essentiality; alternatives that exist

There are proven effective alternatives to control mite infestations in beekeeping. However, some are not necessarily any safer to use. For instance, the essential oil wintergreen, which is often put into homemade grease cakes that are placed in the hive, is poisonous; amounts as little as 4 ml can be deadly if ingested. Clearly, wintergreen needs to be handled carefully.[435]

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[433] Ibid.

[434] http://dave-cushman.net/bee/formicsafety.html

[435] http://www.webmd.com/vitamins-supplements/ingredientmono-783-WINTERGREEN.aspx?activeIngredientId=783&activeIngredientName

Thymol is another essential oil that is proven to be effective against mite but warrants caution if handled as an oil. Thymol, like formic acid, can kill some bees in weaker colonies. However, there are prepackaged gel pads available, such as **Apigard**, that are **safer to use for the beekeeper** although there are substantiated reports of significant brood kill when using the product at temperatures hotter than 90 degrees.[436]

Some beekeepers suggest that dusting bees with powdered sugar makes it difficult for the mites to adhere to the bees. However, research does not support the claims that it is effective.[437] Randy Oliver, the author of *Scientific Beekeeping,* suggests that the practice could provide some relief from mite infestation but only if done on a weekly basis; even then, it is only mildly effective.[438]

Last, but certainly not least, as mentioned above, is the prevention of mites **through proper selection of naturally resistant bees**. This is likely the **most effective long-term strategy and should be promoted as the primary sustainable way to control mites**, as well as other parasites and diseases in honey bees.

Livestock Subcommittee action

July 7, 2015: The subcommittee motion to remove formic acid from §205.603 as a treatment for livestock was Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

CONCLUSION

The Cornucopia Institute recommends keeping formic acid on the National List, as it is an effective tool for treating mites when necessary, **provided that an annotation is added limiting its use to the safer and readily available pretreated pads and only after fulfilling a requirement for the producer to attempt to control pests with natural alternatives and/or breeding**.

However, Cornucopia strongly encourages the development and propagation of pest- and disease-resistant livestock in organic agriculture, including beekeeping, to limit and minimize the dependence on the use of potentially harmful chemicals.

[436] http://scientificbeekeeping.com/ipm-7-the-arsenal-natural-treatments-part-2/
[437] Berry, J., Afik, O., Nolan IV, Ohad, Delaplane, K. Revisiting Powdered Sugar for Varroa Mite Control on Honey Bees. Journal of Apicultural Research 51(4): 367-368 (2012)
[438] http://scientificbeekeeping.com/powdered-sugar-dusting-sweet-and-safe-but-does-it-really-work-part-1/

Hydrogen Peroxide – 2017 Sunset

SUMMARY

The Cornucopia Institute **supports the relisting of hydrogen peroxide** at §205.603(a) for its current livestock uses.

DISCUSSION

Hydrogen peroxide is a small inorganic molecule comprised of two hydrogen atoms and two oxygen atoms with a molecular formula of H_2O_2. As a peroxy compound, hydrogen peroxide contains a highly reactive oxygen-oxygen single bond. Hydrogen peroxide is inherently unstable due to the weak peroxide (O–O) bond. At typical commercial concentrations, hydrogen peroxide is expected to degrade rapidly to water and oxygen.[439]

USDA organic regulations currently allow the use of hydrogen peroxide in organic crop production as an algicide, disinfectant, and sanitizer, and for plant disease control as a fungicide. Likewise, hydrogen peroxide is also permitted for use in organic livestock production as a disinfectant, sanitizer, and medical treatment. Lastly, synthetic hydrogen peroxide may be used as an ingredient in or on processed products labeled as "organic" or "made with organic" foods.

A new Technical Review was published in 2015, but it is deficient due to only evaluating the material for crop production. Although it provides some of the information needed to evaluate this material for livestock production, it does not discuss the efficacy of hydrogen peroxide as a germicide or teat dip for common livestock pathogens, nor does it discuss potential health concerns when used on or around livestock.

Human health concerns

According to the Agency for Toxic Substances and Disease Registry (ATSDR), hydrogen peroxide is unlikely to cause chronic toxicity because it is rapidly decomposed in mammalian bodies. However, repeat exposure to vapors of hydrogen peroxide may cause chronic irritation of the respiratory tract and even partial or complete lung collapse.[440] Hydrogen peroxide is a known mutagen and is exhibits genotoxicity in mammalian and human cell lines.[441,442] The International Agency for Research on Cancer (IARC) determined

[439] US EPA. (2007). Peroxy Compounds: Hydrogen Peroxide and Peroxyacetic Acid Environmental Fate Science Chapter. US Environmental Protection Agency.
[440] ATSDR. (2014). Medical Management Guidelines for Hydrogen Peroxide. Agency for Toxic Substances & Disease Registry.
[441] IARC. (1999). IARC Monographs on the Evaluation of Carcinogenic Risks to Humans: Hydrogen Peroxide. International Agency for Research on Cancer.
[442] Driessens N, Versteyhe S, Ghaddhab C, Burniat A, De Deken X, Van Sande J, et al. (2009). Hydrogen peroxide induces DNA single-and double-strand breaks in thyroid cells and is therefore a potential mutagen for this organ. Endocrine Related Cancer 16:845–856.

that there is inadequate evidence in humans and limited evidence in experimental animals demonstrating carcinogenicity of hydrogen peroxide, classifying the substance as Group 3 – *Not classifiable as to its carcinogenicity to humans.*[443]

Environmental concerns

Contamination is not expected when purified forms of hydrogen peroxide are released into the environment following normal use. At typical concentrations, hydrogen peroxide is expected to rapidly degrade to oxygen gas and water.[444]

Efficacy

Hydrogen peroxide is a readily available, affordable disinfectant. It is considered a broad-spectrum germicide effective against most mastitis-causing bacteria. The "fizzing" action of hydrogen peroxide helps to clean the teats, making it an excellent pre-dip.[445] It is even more effective when combined with lactic acid or other acids (i.e., ascorbic) to remove dead skin cells from the teats. Emollients such as glycerin are also added to hydrogen peroxide-containing dips to protect against the drying action of this disinfectant and prevent damage to the teats.

Although there are only a few National Mastitis Council protocol studies on hydrogen peroxide, the anecdotal data is quite good and there exist challenge tests that indicate its effectiveness against the major mastitis-causing pathogens. It also has a shorter shelf life and is photosensitive.

NOSB Livestock Subcommittee action

June 16, 2015: The lead looked at previous NOSB recommendations and public comment. A large spectrum of stakeholders support relisting.

The vote to remove hydrogen peroxide from §205.603(a) was Yes: 0, No: 6

CONCLUSION

Based on the limited risks to humans, animals, and the environment, as well as its efficacy, The Cornucopia Institute **recommends relisting hydrogen peroxide at §205.603(a)** for livestock uses.

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[443] IARC. (2014). Agents Classified by the IARC Monographs, Volumes 1–111. International Agency for Research on Cancer.

[444] US EPA. (2007). Peroxy Compounds: Hydrogen Peroxide and Peroxyacetic Acid Environmental Fate Science Chapter. US Environmental Protection Agency.

[445] Belsito, Jessica. (2012). Alternative teat dips: Weighing cost and quality. *Progressive Dairyman*. March 16, 2012.

Lidocaine – 2017 Sunset

SUMMARY

The Cornucopia Institute **supports the relisting** of lidocaine on the National List under §205.603 Synthetic substances allowed for use in organic livestock production, and **supports** an annotation reducing the withholding period for meat and dairy from treated animals.

Rationale:

- Lidocaine is a relatively safe, effective, widely available, local anesthetic used to reduce pain in an animal during veterinary surgical procedure or during dehorning.
- Potential toxicity is minimal when used appropriately.
- Safe and effective non-synthetic alternatives are not available.
- A 90-day withholding period seems excessive and shorter withholding periods are supported by research. The five-day withholding period recommended by the Livestock Subcommittee is appropriate.

DISCUSSION

The synthetic drug 2% lidocaine hydrochloride was first approved for use in organic livestock production in 1995. In commercial use since 1949, and as the only anesthetic approved for cattle by the FDA,[446] lidocaine has become the mostly commonly used local anesthetic in veterinary medicine in the U.S.[447] It is also considered the most effective, as it is short acting and longer lasting than other commonly available local anesthetics such as procaine.[448]

Lidocaine hydrochloride is a water soluble injectable drug that acts quickly to numb an injection site to reduce the feeling of pain. It is regularly used for reducing pain during surgery or dehorning, for treating painful wounds, or for use as an epidural. While the local synthetic anesthetic procaine can also be used, its action is slower to take effect and does not last as long. Thus, it offers no advantages as an alternative to lidocaine for organic producers.

In a recent survey The Cornucopia Institute conducted with certified organic livestock producers (excluding poultry), 10 farmers out of 28 respondents thus far mentioned that they used the 2% lidocaine hydrochloride on one of their animals for pain relief. This

[446] Geof Smith, DVM, MS, PhD, "Extralabel Use of Anesthetic and Analgesic Compounds in Cattle" Vet Clin Food Anim 29 (2013) 29–45 http://dx.doi.org/10.1016/j.cvfa.2012.11.003

[447] https://instruction.cvhs.okstate.edu/.../pdf/14LocalAnesthesia2006b.pdf

[448] Opinion of the Scientific Committee of the Norwegian Scientific Committee for Food Safety 10 June 2005: Risk assessment of lidocaine residues in food products from cattle, swine, sheep and goats: withdrawal periods for meat and milk. www.vkm.no/dav/8b9b95e522.pdf

probably demonstrates that it is a commonly used drug. Full results from our survey will be presented at the NOSB meeting.

In human medicine use of lidocaine is even more widespread; it is used as an injectable local anesthetic during surgery or dental procedures, and in a wide variety of over-the-counter medications such as wound sprays, liniments, sunburn treatments, and teething gels.

While it is possible to overdose, when lidocaine is used as directed it is considered safe and non-addictive. It is not a drug that is in demand for illicit use. 2% lidocaine hydrochloride is only available for use by a licensed veterinarian or under the direct supervision of a licensed veterinarian.

CONCERNS ABOUT WITHHOLDING INTERVAL

For organic livestock use, withholding of livestock for meat after administering lidocaine is quite long, at 90 days. Withholding for milk is seven days for dairy animals. Whether such a long withholding period is necessary for meat animals is questionable. A very real concern is that the excessively long withholding period may discourage livestock producers from using lidocaine to reduce pain when it would be in the best interest of the animal's welfare to use the drug.

Livestock producers face increasing scrutiny by the general public and media over their care of animals. When a wound, injury, or procedure is likely to cause an animal pain, livestock producers should be encouraged to provide treatment for that pain as the humane treatment of livestock is a priority for both producers and consumers. Therefore, there should not be an unsubstantiated barrier to treating livestock for pain, such as an excessive withholding period for a commonly used, relatively safe drug such as lidocaine hydrochloride.

Drug residues in meat and milk are a cause for concern in modern livestock production, as residues can cause potential health hazards to humans. Withholding periods are set to reduce the risk of any potential hazards. Additionally, the NOP has typically adopted **withholding periods that are double the standard withholding periods for conventional livestock** production, based on consumer perception of the extra precautions taken in organic agriculture. However, given that the **withholding period for meat in conventional, non-organic livestock is only four days**, the **90-day withholding requirement for meat animals in organic production seems excessive** and is not supported by research.[449]

[449] Opinion of the Scientific Committee of the Norwegian Scientific Committee for Food Safety 10 June 2005: Risk assessment of lidocaine residues in food products from cattle, swine, sheep and goats: withdrawal periods for meat and milk. www.vkm.no/dav/8b9b95e522.pdf

Research in dogs, cats, sheep, horses, and rats demonstrates rapid elimination of lidocaine and its metabolites, usually within several days of administration.[450] Research available from cattle suggests that half-lives of drugs are typically shorter in cattle than in dogs and cats or humans.[451] A study completed in 2009 on Holstein dairy cattle demonstrated a total clearance and no-detectable residues in the milk within 36 hours of lidocaine administered as an injected epidural. This study is widely used to support the standard withholding periods of 4 days for meat and 72 hours for dairy.[452]

Following the trend of other synthetic drugs used for organic livestock production, such as xylazine, it seems rational to suggest a withholding period that is double conventional recommendations. In the case of lidocaine, that would mean eight days for meat and six days for milk.

Livestock Subcommittee action

May 19, 2015:
Lidocaine was evaluated against the OFPA criteria and found to satisfy them all. The vote to remove lidocaine from §205.603 Yes: 0, No: 6.

The lead indicated that she will develop a proposal to modify/reduce the withdrawal period.

July 21, 2015:
Lidocaine and Procaine - Annotation Change. The Livestock Subcommittee voted previously against removing lidocaine and procaine as part of sunset review but is developing a separate proposal to change the annotations. The subcommittee proposed questions about a reduced withholding time, and commenters, including several producers and organizations, were supportive of the step-down. The lead indicated that there is strong science behind this idea. The lead made some modifications to the draft document based on the discussion.

Motion to change annotations for lidocaine and procaine on §205.603
Lidocaine - as a local anesthetic. Use requires a withdrawal period of ~~90 days after administering to livestock intended for slaughter and 7 days after administering to dairy animals~~ 5 days after administering to livestock.
Procaine—as a local anesthetic, use requires a withdrawal period of ~~90 days after administering to livestock intended for slaughter and 7 days after administering to dairy animals~~ 5 days after administering to livestock.
Vote: Yes: 4, No: 0

[450] Ibid.
[451] Baggott JD. The Physiological Basis of Veterinary Clinical Pharmacology. Oxford: Blackwell, 2001
[452] Sellers, G., Lin, H. C., Riddell, M. G., Ravis, W. R., Duran, S. H. and Givens, M. D. 2009, Pharmacokinetics of lidocaine in serum and milk of mature Holstein cows. Journal of Veterinary Pharmacology and Therapeutics, 32: 446–450.

August 4, 2015 LS notes:
Lidocaine and procaine. Both of the documents proposing annotation changes were revised and will be put forth as discussion docs instead of proposals. In light of the revisions, the LS chose to revote on the 2017 Sunset proposal to remove procaine. The original vote was conducted on May 19. The LS does not feel that they need a revote on lidocaine, as these changes will not affect the outcome of that vote.

Revote:
Additional Discussion: Yes: 4, No: 2
Lidocaine/Procaine annotation change discussion document. THE LS added specific questions for both lidocaine and procaine for which they are seeking public comment.
Motion to accept the Lidocaine/Procaine annotation change discussion document.
Additional Discussion: none Yes: 6, No: 0

CONCLUSION

Lidocaine is a widely used, readily available, relatively safe local anesthetic with no better alternatives. The Cornucopia Institute **supports relisting** of lidocaine at §205.603. Additionally, Cornucopia supports the annotation to shorten the withholding period for meat from 90 days to 5 days after administering to livestock. This withholding time period is in line with what the research shows to be reasonable to reduce the risk of any hazards to human health.

Mineral Oil – 2017 Sunset

SUMMARY

The Cornucopia Institute **cautiously supports** the relisting of **mineral oil** on the National List under §205.603 Synthetic substances allowed for use in organic livestock production.

Rationale:

- Mineral oil is likely to be relatively safe and effective for treating external parasites; however, it may be considered the **most prevalent synthetic contaminant in human bodies** because of its widespread use in food preparation and cosmetics.
- **Scientists have raised questions about its safety** because, despite widespread use, its safety has not been unequivocally established.
- Essentiality for organic livestock production is questionable.

DISCUSSION

Mineral oil is a synthetically **produced byproduct of petroleum** production. In livestock production it is often used both externally to treat parasites such as lice and internally to treat bloat; it is also used as a lubricant to help livestock pass internal obstructions. However, in organic livestock production it is allowed only for use externally as a topically applied substance.

The Cornucopia Institute is neutral on the relisting of this substance. It is effective at reducing or eliminating external parasites, such as lice, on livestock. However, there are questions as to its safety, which has not been scientifically established, and the essentiality of this product for livestock production is questionable.

Mineral oil is generally considered safe for topical use. As it is inexpensive, it is one of the most commonly used ingredients in health and beauty products such as moisturizers; moreover, it is the main ingredient in products sold as "baby oil." It also is often used as a lubricant in the food industry because it is non-reactive and doesn't become rancid.

As a topically applied parasiticide on livestock, it effectively kills lice and mange mite by suffocating them. The insects need oxygen to breathe, but the oil coats their exoskeletons preventing oxygen absorption.

However, it is unknown just how prevalent mineral oil use is for controlling external parasites in organic livestock. One reason is that lice, while often common on cattle in late winter and early spring, are rarely an economic concern. Lice cause itching and cattle will often rub off some hair. However, cattle do not normally suffer any loss of production or any obvious negative consequences to their health due to lice, so many cattle producers do not provide any kind of treatment.

Another reason is that the price of mineral oil is much higher than diesel fuel, which is the most commonly used product for external parasite control in conventional cattle

production. Diesel fuel is often mixed with an insecticide, which is poured into cattle oilers, sometimes called back rubbers. Cattle rub on the oilers, which wick the product onto their hide, a practice banned in organics.

International regulations

IFOAM Basic Standards do not allow for the use of mineral oil in livestock production.

Canadian Organic Standards, which are similar to those in the U.S., allow for the external use of mineral oil in livestock production.

Human health concerns

Mineral oil is considered to be a large contaminant in our bodies because of its widespread use in food preparation and in cosmetics. Recently, scientists have expressed concern that its safety has never been fully established. The authors of a 2008 editorial in the *European Journal of Lipid Science and Technology* state, "Presently there is insufficient knowledge about potential negative effects of mineral oil on human health."[453]

While it is not considered carcinogenic or toxic, there are concerns about its potential effects on the endocrine system. A study published in 2010 found that mineral oil does have possible endocrine disrupting potential.[454]

Environmental concerns

There do not appear to be any specific environmental issues associated with proper use of mineral oil as it is not used in large enough quantities to merit concern (outside of concerns regarding the general production practices and transportation of petroleum products).

Essentiality; alternatives that exist

The primary alternative to mineral oil is to not treat livestock for lice and select cattle that are resistant to lice. Lice cause some itching and discomfort and cattle will rub off some of their hair coat. However, lice are normally only a problem for a month or two during the late winter and early spring. As springtime approaches their hair coat is restored and the lice disappear.

While topically applied vegetable oils can have the same suffocating effect as mineral oil on external parasites, cattle will also readily consume those oils, licking them off of each other, lessening their effectiveness. In addition, vegetable oils will become rancid, unlike mineral oil.

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[453] Koni Grob, Koni. Does the Ukrainian sunflower oil contaminated with mineral oil wake up sleeping dogs? *European Journal of Lipid Science and Technology*, Vol. 110, Issue 11; November 2008 DOI:10.1002/ejlt.200800234

[454] Vrabie CM1, Candido A, van Duursen MB, Jonker MT. Specific in vitro toxicity of crude and refined petroleum products: II. Estrogen (alpha and beta) and androgen receptor-mediated responses in yeast assays. Environ Toxicol Chem. 2010 Jul;29(7):1529-36. doi: 10.1002/etc.187.

Water-based herbal sprays and washes for cattle exist, but because of their water solubility they wash off within days and have to be applied more often than oil-based products. Mineral oil can be used in cattle oilers, which enable the cattle to self-apply the product, whereas water-based substitute substances can't be used in cattle oilers, because they evaporate too quickly and therefore require manual application, which results in significantly more labor.

Livestock Subcommittee action

July 21, 2015: Few comments were received about mineral oil. A member asked about using vegetable oil as a substitute. Another member noted that mineral oil is preferable as it does not go rancid.

The subcommittee motion to remove mineral oil from §205.603 as a treatment for livestock was Yes: 1 No: 3 Abstain: 1 Absent: 1 Recuse: 0

CONCLUSION

The Cornucopia Institute cautiously supports the relisting of mineral oil on the National List under §205.603 Synthetic substances allowed for use in organic livestock production. Cornucopia feels the question of essentiality of mineral oil for sustainable, humane livestock production requires further exploration. Additionally, concerns exist about mineral oil being a possible endocrine disruptor.

Parasiticides/Anthelmintics – 2017 Sunset

Table 4: Comparison of NOP-approved Synthetic Parasiticides

Parasiticide	Ivermectin	Moxidectin	Fenbendazole
Properties	• Chemical class: Macrocyclic Lactone • Use on: Cattle, sheep, goats (not approved by FDA but can be used for "extra-label" reasons if directed by vet), swine, poultry • Cannot be used on dairy animals • Withdrawal (FDA label requirements, not NOP): 35 days for cattle, 11 days for sheep, 14 days goats, 18 days for swine • Administered as: drench, injection, paste, feed additive, capsule, powder, & pour-on	• Chemical class: Macrocyclic Lactone • Use on: Cattle, sheep, goats (not approved by FDA but can be used for "extra-label" reasons if directed by vet), deer • Can be used on dairy animals topically (not under NOP rules though) • Withdrawal (FDA label requirements, not NOP): 0 days for cattle, 17 days goats • Administered as: pour-on, drench, injectable	• Chemical class: Benzimidazoles • Use on: Cattle, sheep, goats, swine, poultry • Can be used on dairy animals but only in a few formulations (paste, oral suspension, feed additive) • Withdrawal (FDA label requirements, not NOP): 8 days for cattle, 0 days swine, 16 days goats (longer for bolus administrations) • Administered as: drench, feed additive, capsule, bolus, tablet, pill
Effective Against	• Redworms • Pinworms • Roundworms • Stomach hair worms • Large-mouthed stomach worms • Neck and intestinal threadworms • Mites, lice • Bots	• Roundworms • Lungworms • Cattle grubs • Mites • Lice • Horn flies • Cattle ticks	• Redworms • Pinworms • Roundworms • Lungworms • Stomach hair worms • Large-mouthed stomach worms • Tapeworms
Advantages	• Effective against a greater number of parasites than Fenbendazole • Ivermec products are readily available in OTC products • More ways to administer this material	• Not soluble in water, therefore not toxic to aquatic organisms	• More target spectrum of activity • More benign to earthworms, microorganisms, & dung beetles than avermectins • Less resistance issues than with Ivermec products • Can be added to feed; don't need to inject

			• Dung pats treated with fecally-excreted fenbendazole were reduced to a granular and crumbling structure after 42 days[455]. This could be considered an advantage over Ivermectin, which inhibited organic matter breakdown much more.
Disadvantages	• Not effective on tapeworms or flukes, fleas, or horse/stable flies • Found to be toxic to aquatic daphnids, which are small planktonic crustaceans that live in freshwater, therefore manure run-off from fields should be prevented if animals have been recently treated[456] • Can be toxic to certain soil invertebrate species, but at levels that are environmentally unrealistic[457] • Certain parasites can build resistance. There are methods to slow resistance build-up, but none to stop it[458] [459],	• Cross resistance with Ivermectin • Binds tightly to soil; long half-lie of up to 6 months • Adverse effects on non-target soil organisms	• Not effective on flukes or external parasites (mites, lice, flies, etc.) • Not available as an injectable or pour-on in this country • Caused tumor growth in lab mice[460] • Just like Ivermectin, has 'non-target effects' on dung breeding insects and manure degradation[461] • Highly toxic to zebrafish[462] • Also like Ivermectin, certain parasite species can build resistance to Fenbendazole[463]

[455] Strong, L., R. Wall, A. Woolford, D. Djeddour. (1996). The effect of faecally excreted administration of sustained-release boluses. *Veterinary Parasitology*. 62(3-4): 253-266.
[456] Lopes, C., S. Charles, B. Vollat, J. Garric. (2010). Toxicity of ivermectin on cladocerans: Comparison of toxic effects on *Daphnia and Ceriodaphnia* species, 2010. *Environmental Toxicology and Chemistry*. 28(10): 2160-2166.
[457] Jensen, J., P.H. Krogh, L. E. Sverdrup. (2003). Effects of the antibacterial agents tiamulin, olanquindox and metronidazole and the anthelmintic ivermectin on the soil invertebrate species Folsomia fimetaria (Collembola) and Enchytraeus crypticus (Enchytraeidae). *Chemosphere*. 50(3): 437-443.
[458] Dent, J.A., M.M. Smith, D. K. Vassilatis, L. Avery. (2000). The genetics of Ivermectin resistance in *Caenorhabditis elegans. PNAS.* 97(6): 2674-2679.
[459] Osei-Atweneboana, M. Y., K. Awadzi, S. K. Attah, D.A. Boakye, J.O. Gyapong, R. K. Prichard. (2011). Phenotypic Evidence of Emerging Ivermectin Resistance in *Onchocerca volvulus*. *PLOS Neglected Tropical Diseases*. 5(3).

	• After 42 days, dung pats containing fecally-excreted Ivermectin were solid and compacted compared to those that didn't contain Ivermectin (Strong et al. 1996) • Ivermectin products only have between 40% and 70% efficacy at reducing fecal egg count, due to increasing parasite resistance to it.		

Ivermectin

SUMMARY

The Cornucopia Institute **opposes the relisting of ivermectin** at §205.603 as a parasiticide in support of the NOSB Livestock Subcommittee's 5:1 vote to remove ivermectin on June 2, 2105.

DISCUSSION

Ivermectin is part of a class of chemical compounds called the "macrocyclic lactones." Ivermectin is in the macrocyclic lactone subgroup of **avermectins.** They are obtained in fermentation processes using *Streptomyces* and subsequent purification and/or chemical modification of the fermentation products. Ivermectin stimulates the release of gamma amino butyric acid (GABA) from nerve endings and enhances binding of GABA to special receptors at nerve junctions. This suppresses nerve impulses, leading to paralysis and eventually death of the parasite. The mode of action is similar for both nematodes and arthropods. Ivermectin is a broad-spectrum parasiticide and displays antimicrobial activity, which has led some sources to consider it an "antibiotic."

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[460] Duan, Q., Y. Liu, C.J. Booth, S. Rockwell. (2012). Use of Fenbendazole-Containing Therapeutic Diets for Mice in Experimental Cancer Therapy Studies, 2012. *J. Am. Assoc. Lab Animal Science*. 51(2): 224-230.

[461] Floate, K.D., K.G. Wardhaugh, A.B. Boxall, T. N. Sherratt. (2005). Fecal Residues of Veterinary Parasiticides: Nontarget Effects in the Pasture Environment. *Annual Review of Entomology*. 50:153-179.

[462] Carlsson, G., J. Patring, J. Kreuger, L. Norrgren, A. Oskarsson. (2013). Toxicity of 15 veterinary pharmaceuticals in zebrafish (Danio rerio) embryos. *Aquatic Toxicology*. Vol 126: 30-41.

[463] Mejia, M.E., B.M. Fernandez Igartua, E.E. Schmidt, J. Cabaret. (2003). Multispecies and multiple anthelmintic resistance on cattle nematodes in a farm in Argentina: the beginning of high resistance? *Veterinary Research*. 34(4): 461-467.

If ivermectin is considered an antibiotic, it is difficult to reconcile its use given the categorical prohibition on antibiotics for use in organic systems.

Parasiticide use has been tolerated in organic livestock production on a limited basis to alleviate animal suffering. To let an animal die because of an extensive parasite infection is inhumane and also not compatible with a system of sustainable agriculture. However, the parasiticide fenbendazole is effective and much more environmentally benign.[464]

Environmental concerns

The avermectins, of which ivermectin is a part, are **extremely broad-spectrum biocidal agents and are variably categorized as parasiticide, anthelmintics, acaricides, insecticides, or macrolide antibiotics**.

Free ivermectin will bind to the soil. Once in the soil, as well as in the feces, ivermectin has been linked to the **killing of dung beetles**.[465] The same study showed that fenbendazole did not have the same toxic effects on dung beetles. Another study from Ohio State University confirmed that fecal concentrations of cattle given ivermectin were lethal or sublethal to many dung breeding invertebrates beneficial to the ecosystem. This result was replicated in subsequent studies.[466]

A 2002 study showed that six commonly used veterinary medications (including both ivermectin and fenbendazole) caused livestock manure to more slowly decay, which likely indicates a negative effect on dung beetles or on the decaying microorganisms that normally would break down the manure in a matter of a few months.[467] **If livestock manure breaks down more slowly, not only can it harbor more parasites and fly larvae but this also prevents the recycling of nutrients that is so essential for good manure management**. Vegetation also does not grow well under intact manure, which over time means a degradation of pasture health.

Human and livestock health concerns

Because many macrocyclic lactones are lipophilic (meaning they have an affinity to fats and do not dissolve well in water), **substantial concentrations will be found in edible tissues of the livestock**. As much as 5% of the administered drug can be secreted in the

[464] Wall, R. and L. Strong. (1987). Environmental Consequences of Treating Cattle with the Antiparasitic Drug Ivermectin. *Nature* 327: 418-421.
[465] Ibid.
[466] Madsen, M. (1990). Treating cattle with Ivermectin: Effects on the Fauna and decomposition of dung pats. *Journal of Applied Ecology*. 27: 1-15.
[467] Sommer, C. and B.M. Bibby. (2002). The influence of veterinary medicines on the decomposition of dung organic matter in soil. *European Journal of Soil Biology*. 38(2): 155-159.

animals' milk. For this reason, ivermectin is not approved for use on dairy animals (but topical moxidectin, another macrocyclic lactone, is).[468]

Alternatives and essentiality

All three of these parasiticides described in these comments have shown some problems with variable levels of resistance development by some parasites. The research is not really conclusive; what works on one farm or one flock/herd of animals may not work on another. Because of this, it is important to first identify which parasites are present and at what levels. If the levels of parasitism require intervention and all other methods have failed, then a farmer must pick the parasiticide most effective against that particular parasite. The table above displays the variations in efficacy against different parasites by different wormers. If a wormer used by a producer doesn't appear to offer the desired control, a different one may have to be tried. This is one reason why it is important to have a few choices of anthelmintics in case the parasites are showing resistance to one of the wormers.

There are also many alternatives to using synthetic parasiticides and restricted use requirements should favor these. As with all livestock diseases, organic farmers should implement a variety of *preventative* practices to avoid having parasite issues. Some alternatives include: selection of disease-resistant breeds and breeding stock, culling susceptible animals (roughly 10%-15% of a herd will shed 80% of the parasite eggs), rotational grazing, preventing overgrazing (in which the livestock is forced to eat lower on the plants where the larvae tend to accumulate), planting of naturally anthelmintic plants in the pastures (*Sericea lespedeza*, chicory, and plantain are a few examples), and other management approaches. Natural remedies once an animal has parasites may include garlic, wormwood, psyllium, quassia, pumpkin seed meal, papaya seeds, diatomaceous earth, activated charcoal, and other methods, although their efficacy is unconvincing.[469],[470] Jackson-O'Brien's research showed that a pumpkin seed meal oral drench showed some promise, but that garlic, ginger, and papaya seeds show no efficacy.

Preliminary Results of Cornucopia's Certified Organic Livestock Producer Survey

In our latest survey of certified organic livestock producers, 32% said that they used at least one of these three synthetic wormers on occasion, the most common being ivermectin (7 out of 28 respondents).

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[468] Baynes, R.E., M. Payne, T.M. Jimenez, A.R. Abdullah, K.L. Anderson, A.I. Webb, A. Craigmill, J.E. Riviere. (2000). Extralabel use of Ivermectin and Moxidectin in food animals. *Veterinary Medicine Today: FARAD Digest*. 217(5): 668-671.

[469] Allen, J., M. Boal, P. Doherty. (1998). Identifying and Testing Alternative Parasiticides for Use in the Production of Organic Lamb. *Organic Farming Research Foundation Final Report* 98-03.

[470] Jackson-O'Brien, D.(2012). Efficacy of Natural Dewormers in the Control of Gastrointestinal Nematodes of Small Ruminants. *Sustainable Agriculture Research and Education (SARE)*. Northeast SARE 2012 Final Report

Alternatives to utilizing chemical wormers that were mentioned by survey respondents include (by order of frequency): diatomaceous earth (7), pumpkins or pumpkin seeds (2), Pyganic (1), rotational grazing (1), keeping a closed herd (1), homeopathy (1), copper boluses (1), garlic (1), herbs (1), and Neem-a-tox (1). Several mentioned that much more research needs to go into alternatives to synthetic wormers as parasites are an ongoing issue for almost every livestock producer, regardless of how well they farm. There will always be some level of parasite colonization in livestock.

Compatibility with organic agriculture

In light of the NOSB's other policies on animal health, use of such materials would not be considered compatible with a system of organic agriculture. The administration of any synthetic anthelmintics would result in the loss of organic status of the animal. However, the long withdrawal periods required in the annotations (90 days for dairy animals, last third of gestation for breeding stock, prohibited in slaughter stock completely) are believed by some to be a reasonable compromise instead of a complete loss of the organic status for the animals. In any case, just as in the administration of therapeutic antibiotics, producers should not withhold treatment from infested animals to have them considered organic. Such animals must be treated and diverted to the conventional market if necessary.

Compatibility with a system of sustainable agriculture must be evaluated on several levels. One is the welfare of the animals being raised. In addition to alleviating animal suffering related to itching and a failure to thrive, parasites can have more serious consequences for the animals themselves. Internal parasitism is a common cause of anemia in small ruminants.[471] In fact, a frequent reason for using anthelmintics in small ruminants is salvage (i.e., treatment to save the life of the animal), not just parasite control.[472] Also, a very infected, wormy animal will often be condemned by USDA inspectors at slaughter, so there is an additional economic loss from parasitism.

Yet sustainability of synthetic parasiticides will always be compromised by interdependent factors such as the underdosing of animals by owners treating their own livestock (or worming the entire herd whether needed or not), leading to an increase in anthelmintic resistance, environmental contamination, and resulting in greater use of anthelmintics with lower control achieved. Therefore, the NOSB should not concern itself with whether or not infected animals should be treated; the consensus is that they should. The real question is what to do with treated animals and what to do with operations that regularly use synthetic parasiticides prophylactically on a large portion of their herds. Again, the annotations prohibit routine use, so this should not be an issue for certified organic operations.

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[471] Waldridge, B.M. (1998). Weight Loss and lethargy: diagnostic challenge. *Veterinary Forum* (May): 72-73.

[472] Luginbuhl J. M. (1997). Roundworms in goat herds. Livestock Newsletter. http://jackson.ces.stat.nc.us/newsletters/livestock/jan-feb97

Is the use of synthetic parasiticides, even with the restrictive annotation, compatible with the principles and practice of organic agriculture? This is an especially poignant question as some experts view this material as an "antibiotic." However, from an animal welfare perspective, when parasiticides such as ivermectin are used, as a last resort to save the life of an animal, they are certainly necessary. The question is should that animal be forced to be diverted from organic production as is in the case after administration of therapeutic antibiotics. In regards to the use of Ivermectin, the answer is yes.

Livestock Subcommittee action

On June 2, 2015, the Livestock Subcommittee found that ivermectin failed to meet the OFPA criteria regarding environmental impacts, because it is harmful to dung beetles and soil biology. Motion to remove ivermectin from §205.603 Yes: 5, No: 1, Absent: 2

CONCLUSION

The Cornucopia Institute is **opposed to the relisting of ivermectin** on §205.603 as a restricted parasiticide. Ivermectin is harmful to dung beetles and soil life, can act as an antibiotic, and is not consistent with OFPA criteria.

Moxidectin

SUMMARY

The Cornucopia Institute is **supports the relisting of moxidectin** at §205.603 as a parasiticide with the following annotation:

> *Prohibited in slaughter stock, allowed in emergency treatment for dairy and breeder stock when organic system plan-approved preventive management does not prevent infestation. Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for 90 days following treatment. In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic and must not be used during the lactation period for breeding stock. Synthetic parasiticides must not be administered on a routine basis. For control of internal parasites only.*

DISCUSSION

Moxidectin is part of a class of chemical compounds called the "macrocyclic lactones," like ivermectin. They are obtained in fermentation processes using *Streptomyces* and subsequent purification and/or chemical modification of the fermentation products. Moxidectin (MOX) is in the macrocyclic lactone subgroup of **milbemycins.** All macrocyclic lactones have a systemic mode of action, i.e., after injection, ingestion, or topical

administration they get into the blood stream of the host and are transported "everywhere" to kill the parasites.

Topically applied endectocides like moxidectin can also act on the external parasites by **contact.** Although moxidectin is efficacious against many external parasites, the NOP listing annotation prohibits external use, citing their concerns about the long half-life of moxidectin in the soil, which has since been shown to be much shorter, more like two months rather than the six months mentioned by the Livestock Subcommittee in 2004.[473]

The value of moxidectin is that it provides a proven alternative to ivermectin, which should be removed from §205.603, and it gives producers a product to rotate with fenbendazole to prevent parasites from developing resistance to either product.

The new TR was not made available to the public until June 2015. This is totally unacceptable as it impedes efforts by citizens and organizations to make informed, **timely**, summary reviews of critical, and potentially controversy, substances of this nature.

Environmental concerns

The residual toxicity of moxidectin in manure has been tested mainly for two species of dung beetles, *Euoniticellus intermedius* and *Digitonthophagus gazella*. For both species, residues present in dung of cattle treated 1 to 42 days previously with MOX in an injectable or topical formulation had no effect on reproductive success.[474] Different studies have concluded that moxidectin appears to be less harmful to arthropods than other endectocides (parasiticides that can be used internally and externally) such as ivermectin. Additional research indicates that moxidectin, when administered at the recommended dosage, is unlikely as well to have an adverse effect on earthworms.

According to the 2003 TAP report, the lipophilic nature of this substance causes it to bind tightly to the soil matrix; thus, it is not likely to contaminate water sources or harm aquatic organisms.

Human and livestock health concerns

Moxidectin may be irritating to the eyes and skin of humans. If properly handled, this should not be an issue.

Since moxidectin is approved for use on dairy animals, it is important to consider the potential residues that may end up in the milk of those animals. A 2004 study showed that both ivermectin and moxidectin residues were detectable in the raw milk of dairy sheep

[473] Moxidectin TAP Report 2003

[474] Lumaret, J.P., F. Errouissi, K. Floate, J. Rombke, K. Wardhaugh. (2012). A Review on the Toxicity and Non-Target Effects of Macrocyclic Lactones in Terrestrial and Aquatic Environments. *Current Pharmaceutical Biotechnology*. 13(6): 1004-1060.

and those residues tended to concentrate in the curd and ripening sheep cheese.[475] However, the 90-day withdrawal period for dairy animals in the annotation (meaning that milk has to either be sold as conventional or dumped) was thought to be sufficient to allow complete elimination of all residues of these parasiticides before milking organically again.

Alternatives and essentiality

See the discussion on parasiticide resistance in the ivermectin section above. The same concerns apply to moxidectin.

Also, just as in the ivermectin discussion, there are a variety of management practices that organic farmers can implement to prevent or reduce the incidence of parasitism.

Compatibility with organic agriculture

Also, as noted in the ivermectin discussion, **is the use of parasiticides, even with the restrictive annotation, compatible with the principles and practice of organic agriculture**? This is an especially pointed question as some experts view this material as an antibiotic. However, from an animal welfare perspective, when parasiticides such as moxidectin are used as a last resort to save the life of an animal, they are certainly necessary. The remaining issue is should that animal be removed from organic production as is the case after administration of therapeutic antibiotics.

Livestock Subcommittee action

June 2, 2015: The subcommittee motion to remove moxidectin from §205.603 as a treatment for livestock was Yes: 4, No: 2.

CONCLUSION

The Cornucopia Institute is **supports the relisting of moxidectin on §205.603** as a restricted parasiticide. Moxidectin does not appear to harm dung beetles or soil, and it provides an alternative to ivermectin as a parasiticide product to rotate with fendbendazole to prevent resistance developing in the parasites.

[475] Imperiale, F.A., M.R. Busetti, V.H. Suarez, and C.E. Lanusse. (2004). Milk excretion of ivermectin and moxidectin in dairy sheep: assessment of drug residues during cheese elaboration and ripening period. *Journal of Agricultural Food Chemistry*. 52(20): 6205-11.

Fenbendazole

SUMMARY

The Cornucopia Institute **supports the relisting of fenbendazole** at §205.603a as a parasiticide with the following annotation:

> *Prohibited in slaughter stock. May only be used in emergency treatment for dairy and breeder stock when Organic System Plan–approved preventive management does not prevent infestation. Milk or milk products from a treated animal cannot be represented as organic, either as "100% organic" or as contributing organic ingredients in a "95% organic" or "made with organic" product for 90 days following treatment. In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic and must not be used during the lactation period of breeding stock. Only for use by or on the lawful written order of a licensed veterinarian. Synthetic parasiticides must not be administered on a routine basis.*

DISCUSSION

Fenbendazole is FDA approved for use in feed. It can also be administered as a drench, capsule, slow-release bolus, tablet, and pill. Synthetic anthelmintics such as fenbendazole being reviewed are chemotherapeutics that are manufactured, formulated, and have modes of action **similar or identical to synthetic chemical pesticides and/or antibiotics**. For example, fenbendazole is closely related to the fungicides benomyl and thiabendazole.

The new TR was not made available to the public until June 2015. **This is totally unacceptable** as it impedes efforts by citizens and organizations to make informed, **timely,** summary reviews of critical, and potentially controversy, substances of this nature.

Environmental concerns

The synthesis of fenbendazole involves petrochemicals, such as benzene and amines, which are both **considered to be carcinogenic compounds**. Unlike the other two substances listed above, which are fermentation products from naturally occurring soil bacteria, fenbendazole is an entirely manmade, synthetic substance.

Between 44% and 50% of fenbendazole is excreted unchanged in the feces in sheep, cattle, and pigs, with the greatest number of metabolites occurring in pigs.[476] As noted in Table 4, above, there is evidence that this parasiticide is toxic to zebrafish, so high levels of excretions like this are definitely a concern.

[476] Adams HR. 1995. Veterinary Pharmaceuticals and Therapeutics, 7th edition. Ames: Iowa State University Press.

Some research shows that fenbendazole is less toxic to dung beetles and other dung decomposers than the avermectins, but there are still some toxicity issues.

Human and livestock health concerns

One study showed tumor growth in lab rats administered fenbendazole.[477]

Just like the other parasiticides, certain parasites are developing resistance to fenbendazole, meaning its usefulness for livestock can be reduced over time in certain cases.

Alternatives and essentiality

Understanding the life cycles of parasites is key to preventing new infections in livestock. Preventing animals from bedding on top of their dung or coming into contact with a fair amount of fresh dung not yet decomposed are some ways to break the parasite cycle.

Other methods include rotational grazing, conducting regular fecal examination, culling heavily infected animals, selecting resistant breeds and breeding stock, and employing biological control during susceptible (usually free-living) stages in the parasite life cycle. While some non-synthetic herbal remedies, botanicals, and mined minerals (such as garlic, black walnut, pumpkin seeds, cayenne pepper, diatomaceous earth, etc.) are claimed to have anthelmintic properties, the efficacy of many of these materials has not been tested in controlled experimental trials.[478,479]

That doesn't imply a lack of effectiveness, as many cultures around the world have utilized herbal anthelmintics for centuries with various degrees of success. In conjunction with better pasture management, there is evidence that organic farming practices, such as green manuring, and a decreasing emphasis on anthelmintic use, increase the abundance and variety of coprophilic microorganisms and arthropods in the dung of pasturing animals which, in turn, act to control fecal forms of intestinal parasites.[480]

Livestock Subcommittee action

On June 2, 2015, fenbendazole was found to satisfy all OFPA criteria. The vote to remove fenbendazole from §205.603 was Yes: 0, No: 6.

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[477] Duan, Q., Y. Liu, C.J. Booth, S. Rockwell. 2012. Use of Fenbendazole-Containing Therapeutic Diets for Mice in Experimental Cancer Therapy Studies. *J. Am. Assoc. Lab Animal Science*. 51(2): 224-230.

[478] Allen, J., M. Boal, P. Doherty. 1998. Identifying and Testing Alternative Parasiticides for Use in the Production of Organic Lamb. *Organic Farming Research Foundation Final Report* 98-03.

[479] Jackson-O'Brien, D. 2012. Efficacy of Natural Dewormers in the Control of Gastrointestinal Nematodes of Small Ruminants. *Sustainable Agriculture Research and Education (SARE)*. Northeast SARE 2012 Final Report

[480] Waller, P.J. and M. Faedo. 1996. The Prospects for Biological Control of the Free-Living Stages of Nematode Parasites of Livestock. *International Journal of Parasitology*. 26: 915-925.

August 18, 2015, from the Livestock Subcommittee notes:
Paraciticides. (Ivermectin, Moxidectin, and Fenbendazole). The LS developed a discussion document in an effort to clarify the annotations. The LS also feels that the withholding periods for these materials are excessive, and will suggest changes. The Subcommittee will include several questions for public comment.

CONCLUSION

The Cornucopia Institute **supports the relisting of fenbendazole at §205.603** as a restricted parasiticide. It is the safest of the synthetic parasiticides and is effective as long as parasites do not develop resistance. However, the organic livestock industry needs to develop sustainable strategies for managing parasites in livestock.

Overall question: Do all three of these parasiticides need to be on the National List §205.603?

The discussion about including synthetic parasiticides on the National List has been lengthy. At the February 1999 NOSB meeting in Washington, D.C., the Livestock Subcommittee Working Session, chaired by Fred Kirshenmann, recorded this in their minutes:

> *Comments on animal medications were again supportive of the NOSB's positions on antibiotic use, which is to ban all antibiotic use for slaughter stock. There are, however, a number of producers who have expressed concern about a ban on the use of parasiticides.*

The exact justification for why parasiticides should be included but antibiotics should not is unclear.

Ivermectin was first approved by the NOSB at the October 1999 meeting, passing 8-3-0. At that same meeting, fenbendazole did not pass, failing 5-6-0. Obviously there were concerns, but the meeting transcriptions don't go into clear detail.

At the first sunset meeting for ivermectin, in 2006, the material failed to get the two-thirds majority to pass (Yes: 6, No: 4, Abstain: 2, Absent: 2), yet, somewhat mysteriously, it remained on the list.

Fenbendazole (officially petitioned in 2007) and moxidectin (petitioned in 2003) were not added to the list of approved synthetic parasiticides until 2012. For a long time the argument was that ivermectin was an effective broad-spectrum parasiticide, but over time it started to lose its efficacy as more and more parasites developed resistance to it. Presumably that is why fenbendazole and moxidectin were finally approved.

Livestock Subcommittee action

At the meeting held June 2, 2015, the Livestock Subcommittee voted Yes: 5, No: 1, to remove ivermectin as it failed to meet OFPA criteria regarding environmental impacts. While some subcommittee members commented that moxidectin should remain on the list as an alternative to fenbendazole to prevent parasite resistance from developing, the subcommittee voted Yes: 4, No: 2, to remove it. The subcommittee voted Yes: 6, No: 0, to keep fenbendazole on the list.

The Cornucopia Institute **supports the relisting of fenbendazole and moxidectin**. These are the more environmentally benign choices and allow producers to rotate products to slow the development of resistance in parasites. The Cornucopia Institute **opposes the relisting of ivermectin** due to the damage it does to valuable insects such as dung beetles and its failure to meet OFPA criteria.

The questionable use of livestock paraciticides is an area of deep concern not just for organic agriculture but for all of livestock production as there is known resistance to all synthetic paraciticides. As mentioned above, The Cornucopia institute stresses the need for the organic livestock industry to develop sustainable strategies for managing parasites in livestock.

Xylazine and Tolazoline – 2017 Sunset

SUMMARY

The Cornucopia Institute **supports the relisting** of xylazine and tolazoline on the National List under §205.603 synthetic substances allowed for use in organic livestock production.

Rationale:

- Xylazine is effective analgesic and sedative used to reduce pain and to immobilize an animal during veterinary surgical procedures.
- Tolazoline is used to quickly and effectively reverse the sedative effects of xylazine to bring animals back to awareness reducing the chance of injury during recovery.
- Potential toxicity is minimal when used appropriately.
- Safe and effective non-synthetic alternatives are not available.

DISCUSSION

The synthetic drugs xylazine and tolazoline are used in combination. Xylazine, which is sold under various trade names, is a sedative as well as an anesthetic. It is generally used in combination with a reversal agent called tolazoline, which is used to bring an animal out of sedation. Since these types of drugs are only used during surgery they are rarely needed by organic farmers. However, when it is necessary to sedate an animal to keep it from moving during surgical procedures, the xylazine/tolazoline combination is an invaluable tool. Performing surgery without sedation would make surgery much more difficult, dangerous and the outcomes more risky—in addition to legitimate questions about the humane treatment of livestock in such circumstances. There are no natural alternatives for use in organic agriculture.

Xylazine and tolazoline are part of a group of synthetic pharmaceuticals approved for use in organic farming in 2007. They were petitioned for use in organic livestock production in 2002 by both livestock producers from CROPP/Organic Valley and Dean Foosd/Horizon, as well as the large animal veterinarians who work with them.[481] There was a concern for the welfare of the livestock during surgical procedures that they would be treated humanely and with the options that would provide for the best outcome for the animal. Up until these were approved, organic livestock producers had to make the difficult choice between using these drugs for use during surgery, and losing organic status for the treated animal.

Sedation of the animal provided by the xylazine immobilizes it so that the procedure can be completed safely and with precision needed for a successful outcome. The drug tolazoline is then used to counter the effects of xylazine and bring the animal out of sedation.

[481] Cornucopia interview with Dr. Hugh Karremen, DVM, former member of the NOSB and its Livestock Subcommittee, April 1, 2015

A quick reversal of sedation with tolazoline is considered an important safety measure. Xylazine hinders rumen mobility and the animal can bloat if rumen motility is not restored.[482] Additionally, tolazoline allows the animal to quickly regain full consciousness and alertness and regain physical abilities in a controlled, supervised manner. While an animal will come out of sedation on its own it will often start trying to move around while it is only semi-conscious, increasing the likelihood of injury. It is during the critical recovery period from surgery, when the animal is regaining consciousness, that it has the highest level of risk of injuring itself.[483]

It's also typical to combine xylazine/tolazoline use with butorphanol, another synthetic anesthetic, for use in surgery. Neuroleptanalgesia is the term used when there both a tranquilizing drug, such as xylazine and an analgesic, such as butorphanol, are administered for relieving surgical pain. Butorphanol serves as the general anesthetic to reduce pain, whereas xylazine serves as a muscle relaxing sedative.[484] The opioid butorphanol (μ or κ agonist) acts synergistically with xylazine (α2-adrenoceptor) for more effective analgesia while allowing for reduced doses of each compound, thus reducing possible side effects from both compounds.[485]

Both xylazine and tolazoline are controlled substances and can only be used by a licensed veterinarian or under a veterinarian's supervision. Xylazine is allowed for emergency situations only and tolazoline is only allowed for use as a reversal agent when xylazine is administered.[486]

It's important to note that while both drugs are not officially allowed for food animal use by the FDA, extra-label or off-label use is legally allowed by licensed veterinarians. In fact, there are no sedative drugs or anesthetic drugs that are FDA approved for use in livestock with the exception of 2% Lidocaine Hydrochloride, in cattle only.[487] Therefore extra-label use of sedative and anesthetic drugs is common in veterinary medicine. Xylazine/tolaxoline are no exception and are widely used by licensed large animal veterinarians for livestock during emergency surgical procedures where a sedative is required.[488]

A weak 2002 TAP review covers the mode of action and describes why and how these are used. However, two of the three reviewers did not agree with the recommendation to allow these drugs for use in organic agriculture. One reviewer only mentioned that because the compounds were synthetic they should not be used, however the reviewer did not suggest any natural alternatives.[489]

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[482] http://www.inchem.org/documents/jecfa/jecmono/v38je03.htm
[483] Cornucopia interview with Dr. Kris Hoffman, DVM, April 2, 2015
[484] http://equimed.com/drugs-and-medications/reference/xylazine>
[485] Dennis R. Geiser DVM and J.E. Henton. "Xylazine and butorphanol: survey of field use in the horse" *Equine Practice* 10.1 (1988): 7-11.
[486] http://www.gpo.gov/fdsys/pkg/CFR-2011-title7-vol3/xml/CFR-2011-title7-vol3-part205.xml#seqnum205.603
[487] Geof Smith, DVM, MS, PhD, "Extralabel Use of Anesthetic and Analgesic Compounds in Cattle" Vet Clin Food Anim 29 (2013) 29–45 http://dx.doi.org/10.1016/j.cvfa.2012.11.003
[488] <http://equimed.com/drugs-and-medications/reference/xylazine
[489] http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5067085

The other critical review suggested that because the compounds were synthetic and were not officially approved for use by the FDA in food producing animals that there must be better options for controlling the animal during surgery than using xylazine for sedation. Unfortunately, the reviewer, an animal science professor, did not provide any suggested alternatives.[vi] However, it's plausible that since none of the reviewers were veterinarians, actively involved in daily animal treatment on livestock operations, they were not aware of the widespread legal, off-label use of these compounds in food producing livestock.
At their September 2002 meeting the NOSB voted to recommend xylazine for emergency use in organic livestock production and to allow tolazoline as a reversal agent for xylazine.

International regulations

IFOAM Basic Standards:
5.7.1.
The well-being of the animals is the primary consideration in the choice of illness treatment. The use of conventional veterinary medicines is allowed when no other justifiable alternative is available.

5.7.2.
Where conventional veterinary medicines are used, the withholding period shall be at least double the legal period.
Canadian Standards do not mention xylazine/tolazoline specifically, but allow for the use of local anesthetics and require a withdrawal period of 90 days after administering to livestock intended for slaughter, and 7 days after administering to dairy animals. Preference is given to natural alternatives.

Human health concerns

Residue sampling of xylanine in sheep, cattle, horses, and dogs demonstrated that concentrations in all species decrease to undetectable levels within a few hours.[490] Due to the withholding periods of eight days for meat animals and four days for dairy animals it is not likely that there are detrimental amounts of xylazine and tolazoline or their metabolites in the meat and milk from treated animals.

Environmental concerns

There do not appear to be any environmental concerns with proper use of xylazine/tolazoline. The drug is rarely used, only in emergency situations, and the dosage amount used in a single animal is very small and breaks down within several hours.

[490] Soback, S. Xylazine monograph. *Residues of some veterinary drugs in animals and foods: FAO Food and Nutrition Paper (41/9).* 1997. http://www.fao.org/docrep/W4601E/w4601e0f.htm

Essentiality; alternatives that exist

The synthetically derived drugs, xylazine/tolazoline are powerful and useful drugs that are widely available through veterinary practices nationwide. They are necessary for sedating and controlling animals during surgery, reducing pain, and for safely reversing sedation. Welfare of the animal must be of primary concern during surgical procedures, which often require the use of anesthesia and sedatives. Xylazine and tolazine appear to be safe and effective when used properly. There are no natural alternatives for organic production.

In a recent survey we conducted with certified organic livestock producers (excluding poultry), only one farmer out of 28 respondents thus far, has mentioned that they used the xylazine/tolazoline combo on one of their animals for a surgical procedure. This probably demonstrates that these substances are rarely needed.

Livestock Subcommittee action

August 4, 2015
Members discussed the FDA status, which had been questioned by public commenters. It is permitted for extra-label use on livestock under the Animal Medicinal Drug Use Clarification Act (AMDUCA) provisions, and a veterinary prescription is required.

Tolazoline is used to reverse effects of Xylazine, which is a sedative, pain and muscle relaxant. Commenters noted that both of these materials are needed.
Vote to remove Tolazoline from §205.603 Yes: 0, No: 5

Xylazine discussion and vote. The lead member on this material, Colehour Bondera, asked about the reference to the FDA and the NOP added that the FDA was consulted, which resulted in the current listing with annotation.
Vote to remove from §205.603 Yes: 0, No: 5

CONCLUSION

Cornucopia institute supports organic livestock producers and the veterinarians who work with them in **recommending** the relisting of xylazine/tolazoline on the National List under §205.603 Synthetic substances allowed for use in organic livestock production.

PETITIONED MATERIAL

Zinc Sulfate

SUMMARY

The Cornucopia Institute is **neutral** on the petition to add zinc sulfate to the National List at §205.603(b) to be used as a footbath only.

Rationale:

- Zinc sulfate appears to be a less toxic material than copper sulfate, the other synthetic material commonly utilized for footbaths.
- The Livestock Subcommittee voted on 2/24/15 (Yes: 4, No: 3, Absent: 1) to list zinc sulfate on the National List at §205.603b as a footbath material. Although this is not a consensus, it does show that there is interest in this material and that a healthy debate was held in subcommittee.
- The Cornucopia Institute would like additional feedback from organic livestock producers before taking a more definitive yes/no stance.
- We do not believe this petition is ready for a full NOSB vote at this time and support sending it back to subcommittee for further review.

DISCUSSION

A petition has been received to allow zinc sulfate to be used as a footbath for control of foot problems (e.g., warts, hoof rot, and abscesses) in livestock, namely dairy cattle, sheep, and goats. Temperature and moisture play an important role in the transmission and invasion of the bacteria that causes hoof problems. 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. Zinc sulfate is already allowed as a feed additive in organic livestock because it provides the important dietary trace mineral zinc. Integrating zinc to the diet is somewhat effective in preventing hoof problems, but does not provide full control.[491]

Regardless of what chemicals are used in livestock footbaths, they must be properly managed. Non-antibiotic footbaths usually contain disinfectants of one kind or another, but large amounts of organic matter on the hooves (manure and dirt) inactivate disinfectants. Therefore, the use of footbaths requires frequent changing of the bath water and/or a pre-rinse; otherwise, footbaths can become an inoculating bath more likely to spread bacteria

[491] Siciliano-Jones, J.L., Socha, M.T., Tomlinson, D. J. and DeFrain, J.M. (2008) Effect of trace mineral source on lactation performance, claw integrity, and fertility of dairy cattle. *J. Dairy Sci.*, 91, pp. 1985–1995.

than kill them. The biggest drawbacks to footbaths are cost, the lack of reliable efficacy data for some treatment methods, and the disposal of the used solution.

In reviewing zinc sulfate, it is important to look at the other NOP-approved synthetic footbath material, copper sulfate, and compare some aspects of the two substances.

Environmental concerns

Commercially, zinc sulfate is manufactured from zinc ore mined from underground or open pit mines. Zinc ore deposits are spread widely throughout the world. The process leading to the manufacturing of zinc sulfate starts with hard rock mining and requires further processing. Emissions from zinc and zinc sulfate production include sulfur dioxide and other gases (sulfur and nitrogen oxides, methane, carbon monoxide, carbon dioxide, nitrous oxide, and ammonia) along with particulate matter and heavy metals such as cadmium and zinc. These are problems not only for the environment (air, water, and soil quality in particular) but also for human health.

One of the biggest environmental problems with footbath solutions is how they are disposed of. Used footbath solutions are typically discarded into the farm lagoon (if a farm has one), washed out with manure or added to composting manure piles. Manure lagoon slurry or composted manure is then usually applied to nearby croplands, leading to potential accumulation of the footbath active ingredients in those soils.

Copper accumulation 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 as well; however, 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 actually be toxic. Unlike copper contamination, excess zinc can be successfully removed from soil by planting sunflower, canola, and other crops.

Zinc is also considered a less toxic material than copper.[492],[493] In one study on metal toxicity to a growing plant (ryegrass), it was shown that the order of toxicity of different metals affecting root growth of seedlings of rye grass was: copper > nickel > manganese > lead > cadmium > zinc > aluminum > mercury > chromium > iron.[494]

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[492] Gupta, U.C. and S.C. Gupta. (1998). Trace element toxicity relationships to crop production and livestock and human health: implications for management. *Communications in Soil Science and Plant Analysis*. 29(11-14): 1491-1522.

[493] Plum, L.M., L. Rink, H. Haase. (2010). The Essential Toxin: Impact of Zinc on Human Health. *Int. J. Environ. Res. Public Health 7*(4): 1342-1365.

[494] Wong, M.H. and A.D. Bradshaw. (2006). A Comparison of the Toxicity of Heavy Metals, Using Root Elongation of Rye Grass, *Lolium Perenne*. *New Phytologist*. 91(2): 255-261.

In an Oregon dairy farm study, soil samples were taken up to 15 inches deep to analyze the zinc and copper concentrations.[495] These farms used both zinc and copper sulfate footbaths and discarded that footbath solution into the manure lagoons. That manure slurry was then sprayed onto adjacent crop fields. Cumulative zinc concentrations ranged from 0.6 to 41.8 ppm, with an average of 10.1 ± 9.3 ppm. Although considerably less than the EPA cumulative loading limit for zinc in soil (2,800 ppm), soil concentrations of zinc at these dairy farms were much higher than the trace element requirements for zinc in crop production. Over time, zinc could accumulate to more toxic levels.

Perhaps more problematic, over 75% of dairy soils tested were considered high (>2 ppm) in copper concentrations and 38% were extremely high (>5 ppm). The study concluded, "Estimates indicate that farms regularly using CuSO4 (copper sulfate) could be applying as much as 4 to 6 kg of Cu/ha annually from the disposal of footbath solutions, which is considered as much as 45 to 50 times the annual Cu needed for most crops." There is increasing concern about the environmental consequences of the disposal of used livestock footbath solutions, specifically if the spent material is improperly remediated prior to dumping into a farm lagoon or onto manure.[496,497]

Another issue for zinc sulfate is its aquatic toxicity. The EPA considers zinc sulfate a pesticide in crop production. On its pesticide label, it reads, "This pesticide is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or public waters unless this product is specifically identified and addressed in a National Pollutant Discharge Elimination System permit." If zinc sulfate footbath liquids are sent into manure lagoons or sprayed onto crop fields, what will prevent them from running off into local waterways? The problem of manure runoff can be particularly acute when dairy farms spray liquid manure onto frozen ground in winter or during the spring or fall rainy periods.

The other NOP-approved footbath material, copper sulfate, is also considered highly toxic to aquatic organisms. It is actually used as an algaecide, so it kills off algae too, depleting oxygen levels in the water and leading to fish kills.

Human health considerations

According to the zinc sulfate Technical Report, many of the most pronounced clinical symptoms in humans are associated with chronically severe or moderate deficiency of zinc, rather than toxic exposure.[498] Powdered zinc sulfate may cause eye, skin, respiratory tract, and digestive tract irritation. Appropriate personal protective equipment is required for

[495] Downing, T., Stiglbauer, K., Gamroth, M.J., and Har, J. (2010) Case study: use of copper sulfate and zinc sulfate in footbaths on Oregon dairies. *Professional Animal Scientist*, 26:3, pp. 332-334.
[496] Ibid.
[497] Anderson, J. L., Peterson, R. C., and Swainson, I. P. (2005) Combined neutron powder and X-ray single-crystal diffraction refinement of the atomic structure and hydrogen bonding of goslarite (ZnSO4·7H2O). *Mineralogical Magazine*, Vol. 69:3, pp. 259-271.
[498] Environmental Protection Agency—EPA (1992) Zinc Salts—Reregistration Eligibility Document, EPA-738-F-92-007.

handling. There is no evidence available to suggest human health hazards associated with excess zinc in meat or dairy products resulting from treatment of livestock with zinc sulfate footbaths. A bigger problem than direct exposure, particularly in farming communities, might be zinc sulfate runoffs finding their way into local waterways, drinking water sources, and potentially groundwater. However, as previously mentioned, copper sulfate is considered a more toxic compound for the environment and humans alike.

Essentiality and alternatives

According to the Livestock Subcommittee proposal, copper sulfate and zinc sulfate are two of the most accepted footbath 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. Salicylic acid (aspirin) has also been shown to be effective in treatment of foot rot in dairy cattle. A combination of tea tree oil, jojoba oil, benzathonium chloride, water, propylene glycol, and emulsifiers (name brand: Hoofmate) as a topical application has been used with some success in treating foot rot.[499] The 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 appears to be much lower than copper or zinc.[500]

Another laboratory-controlled study (not on animals but on agar blocks) looked at the application of heat, essential oils, and sodium for the control of *Trichophyton mentagrophytes* (a fungus that causes foot rot in humans and other animals) and found the following results: The order of the fungicidal activity of 11 essential oils was oregano, thyme thymol, cinnamon bark > lemongrass > clove, palmarose, peppermint, lavender > geranium Bourbon, tea tree > thyme geraniol oils. Minimal fungus concentrations were further reduced to 1/2∼1/8 by the addition of 10% sodium chloride.[501] Although a different organism (*Fusobacterium necrphorum* bacteria) is responsible for most foot rot cases in cattle, the treatments used in this particular study may offer potential for controlling foot rot in livestock.

According to the Technical Report, footbaths containing copper sulfate or formalin were shown to be effective in foot rot treatment for sheep as early as 1933; however, subsequent data clearly indicated that topical application of 10% aqueous zinc sulfate alone produced results as good or better than eleven other treatments including chloramphenicol in 70% ethanol, 70% ethanol, 10% copper sulfate in vinegar, vinegar, copper sulfate and pine tar, copper sulfate in water, formalin in water, dichlorophenol plus hexachlorophene, pine tar

[499] Schivera, D. (2014) Raising organic livestock in Maine: MOFGA accepted health practices, products and ingredients, Maine Organic Farmers and Gardeners Association, Fact Sheets.

[500] Hernandez, J., J.K. Shearer, J.B. Elliott. (1999). Comparison of topical application of oxytetracycline and four nonantibiotic solutions for treatment of papillomatous digital dermatitis in dairy cows. *Journal American Vet Med Assoc*. 214(5):688-90.

[501] Inouye, S., K. Uchida, Y. Nishiyama, Y. Hasumi, H. Yagaguchi, S. Abe. (2007). Combined Effect of Heat, Essential Oils and Salt on the Fungicidal Activity against *Trichophyton mentagrophytes* in Foot Bath, 2007. Japanese Journal of Medical Mycology. 48(1): 27-36.

plus creosote in kerosene and creosote.[502],[503],[504] The efficacy of zinc sulfate in footbaths for sheep was subsequently shown to improve with the addition of the anionic surfactant sodium lauryl sulfate (sodium dodecyl sulfate, SDS) as an excipient. This excipient appeared to promote penetration of zinc sulfate into the ovine hoof. It should be pointed out that of the substances mentioned above, chloramphenicol, formalin, dichlorophenol, hexachlorophene, creosote, and kerosene are not approved for organic production.

Management practices to prevent the incidence and spread of hoof rot include: providing dairy cows with full access to pasture during the summer, housing with flooring that is dry (e.g., automatic scraped slatted floor), long and wide cubicles and increased lying time for heifers, closed herd breeding, prompt treatment of animals with hoof injuries, and reducing the amount of time that animals have to stand on concrete or in wet, muddy conditions.[505],[506]

Preliminary results of Cornucopia's Certified Organic Livestock Producer Survey

Cornucopia sent out a survey in late March 2015 to all certified organic livestock producers (with the exception of poultry). Although we expect more respondents, we got an immediate response from 28 farmers. Of those 28 that completed the survey on their use of livestock materials, 16 said that they used some sort of foot treatment. The most common was copper sulfate (10 use), iodine (2 use), zinc sulfate (2 use), hydrogen peroxide (1 uses), and hydrated lime (1 uses).

Those that do not use foot treatments (12) mentioned they don't need them due to their other prevention practices or that it's just not a problem in their herds. Two mentioned that they try to provide a dry environment for the animals to walk, stand, and lie on, and another mentioned regular foot trimming. Using footbaths may be a more regular practice on larger-scale operations in which the animals may be exposed to more pathogens with animals standing for longer periods of time on unnatural surfaces.

An organic dairy producer we interviewed said he uses a product called Hoofpro in a spray bottle, as infection occurs. He bought four gallons a few years ago and still has three gallons remaining. The spray bottle allows him to use it sparingly and to avoid disposal of a footbath solution. Active ingredients in Hoofpro are copper and sulfur. It is a low pH, ionized copper solution. This farmer also supplies iodine to the cows, such as iodized salt, which seems to reduce hoof warts. He regularly trims his cows' hooves as well. If a particular infection is severe he will soak the hoof in a solution of hydrogen peroxide, then

[502] Murnane, D. (1933) Footrot in sheep, *Journal Counc. Sci. Ind. Res.,* 6, pp. 252-259.
[503] Cross, R.F. (1978) Response of sheep to various topical, oral and parenteral treatments for footrot. *J. Am. Vet Assoc*., 173, pp. 1569-1570.
[504] Cross, R.F. and Parker, C.F. (1981) Zinc sulfate foot bath for control of ovine foot rot, *J. Am. Vet Assoc*., 178, pp. 706-708.
[505] USDA AMS Technical Review: Zinc Sulfate. 2015
[506] Sullivan, Hilary M. (2005). Hairy Foot Warts. New Mexico State University Extension Guide B-122.

bandage for a couple days. He said he is satisfied with his management approach. He doesn't feel like hoof warts are a significant problem in his herd. Perhaps if zinc sulfate or copper sulfate are allowed materials, they should only be used in the same manner as this farmer (spray solution directly onto the hoof) instead of a footbath solution. It may be more labor intensive, but results in no disposal issues.

CONCLUSION

It would appear that zinc sulfate is a less toxic alternative to copper sulfate. Perhaps copper sulfate should be removed from the National List and replaced with zinc sulfate. Possibly indicative of the split vote on the subcommittee level, we feel more research is needed on not only the efficacy differences between the two substances but also their relative environmental toxicity. We do not believe that zinc sulfate is ready to be voted on yet and should go back to subcommittee. Therefore, The Cornucopia Institute **remains neutral** on the listing of zinc sulfate on the National List.