




Comments to the National Organic Standards Board

April 27-30, 2015 Meeting
La Jolla, California

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.

The Cornucopia Institute
P.O. Box 126
Cornucopia, WI 54827
608-625-2000 voice
866-861-2214 fax
cultivate@cornucopia.org
www.cornucopia.org

Cover design by Draft Horse Studio | drafthorsestudio.com
Photo sources:
Main photo – Stonebridge Farm, Longmont, Colorado
Top row – dollarphotoclub.com (photo 1), iStockphoto.com (photos 2, 3 and 5), Linley Dixon, Ph.D. (photo 4)

The Cornucopia Institute's

Comments to the

National Organic Standards Board

Spring 2015 Meeting
April 27–30
La Jolla, California

Submitted April 7, 2015

CORNUCOPIA
INSTITUTE

Contents

INTRODUCTION **3**
HANDLING SUBCOMMITTEE **4**
PROPOSALS 4
Glycerin 4
Whole Algal Flour 6
Triethyl Citrate 8
2016 SUNSET MATERIALS 10
Egg White Lysozyme 12
L-Malic Acid 16
Microorganisms 17
Activated Charcoal 19
Peracetic Acid 20
Boiler Chemicals: Octadecylamine, Diethylaminoethanol, and Cyclohexylamine 21
Sodium Acid Pyrophosphate 24
Tetrasodium Pyrophosphate 26
2017 SUNSET MATERIALS 29
Chlorine Materials 29
Magnesium Stearate 39
Colors Derived from Agricultural Products 44
Lecithin, de-oiled 49
Orange Shellac, unbleached 53
Wood Rosin 56
Carnauba Wax 60
CROPS SUBCOMMITTEE **64**
PROPOSALS 64
Exhaust Gas 64
Calcium Sulfate 67
3-decene-2-one 70
DISCUSSION DOCUMENT: CONTAMINATED INPUTS PLAN 73
2016 SUNSET MATERIALS 78
Ferric Phosphate 78
Hydrogen Chloride 81
2017 SUNSET MATERIALS 85
Newspaper or Other Recycled Paper 85
Ammonium Soaps 87
Lime Sulfur and Elemental Sulfur 93
Soaps, insecticidal 100
Vitamin D_3 104
Copper Sulfate & Fixed Copper Products 108
Lignin Sulfonate 112
Ethylene Gas 117
Microcrystalline Cheesewax 120

LIVESTOCK SUBCOMMITTEE 125
PROPOSALS 125
Methionine 125
Acidified Sodium Chlorite 135
Zinc Sulfate 141
DISCUSSION DOCUMENT: AQUACULTURE 146
2017 SUNSET MATERIALS 149
Iodine 149
Ivermectin 155
Moxidectin 159
Fenbendazole 161
Lidocaine 164
Chlorhexidine 167
Hydrogen Peroxide 169
Ethanol/Isopropanol 171
NANOTECHNOLOGY 174

INTRODUCTION

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.

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.

These comments follow the organization of the Spring 2015 Tentative Agenda released by the USDA National Organic Program, beginning with materials under review by the Handling Subcommittee and concluding with those under review by the Livestock Subcommittee.

Likewise, each subcommittee section follows the Tentative Agenda, beginning with Proposals, followed by Discussion Documents, and concluding with 2016 Sunset Materials and finally 2017 Sunset Materials.

HANDLING SUBCOMMITTEE

PROPOSALS

Glycerin

SUMMARY

Support the reclassification and listing motions that the Handling Subcommittee voted on 12/6/2014 to only allow glycerin derived from agricultural source materials and processed using only biological or mechanical/physical methods to be listed on §205.606 of the National List.

Rationale:

- The Handling Subcommittee spent quite a bit of time studying this complex material and its appropriate listing. On 12/6/14 they took the following votes:
  - **Classification Motion:** Motion to classify glycerin as agricultural when derived from agricultural source material and processed using biological or mechanical/physical methods described under §205.270(a) Yes: 6, No: 0, Absent: 2.
  - **Motion 1:** Motion to list glycerin, produced from agricultural source materials and processed using biological or mechanical/physical methods as described under §205.270(a), at §205.606 Yes: 6, No: 0, Absent: 2.
  - **Motion 2:** Motion to remove glycerin, produced by hydrolysis of fats and oils, from §205.605(b) Yes: 6, No: 0, Absent: 2.
- Certified organic glycerin is not yet produced in sufficient quantities to replace non-organic sources. However, because §205.606 requires that commercially available organic forms of a material must be sought first, and only then can non- organically produced agricultural product be used if organic cannot be procured, this will still encourage the commercialization of organic glycerin.

DISCUSSION

The removal of glycerin as an allowed synthetic has been petitioned by Draco Natural Products, a company that produces certified organic glycerin by means of fermentation of <u>organic</u> corn. This product is agricultural in nature and all the inputs can be acquired from organic sources, according to the petitioner.[1] The synthetic glycerin that is currently used in organic handling is produced by the application of steam or permitted synthetic alkalis

[1] Draco Natural Products. 2013. Petition to remove glycerin from the National List.

such as sodium hydroxide, sodium carbonate, and potassium hydroxide or from the hydrolysis of fats and oils.[2]

Synthetic glycerin is not essential

The motions made by the Handling Subcommittee will cause an allowed synthetic to be replaced by an agriculturally derived source processed using biological means (fermentation) or mechanical/physical means instead. Moving from synthetics to biologically based materials is always a positive progression for the organic rules.

There are a growing number of certified organic glycerin sources. However, comments and testimony provided at the Fall 2014 NOSB meeting indicated that there was still only a fraction of the total glycerin needs being produced organically.

Continued incentive to seek out organic glycerin

Moving glycerin to the National List at §205.606 will require that food processors and handlers seek out organic sources first. Only when they are unable to procure the sufficient quantities they need of organically derived glycerin are they then allowed to purchase non-organic sources. This process will still encourage the continued commercialization of organically produced glycerin.

The development of criteria for evaluating the products of fermentation

The Cornucopia Institute would like to highlight and support the proposal by Beyond Pesticides that the NOSB should address issues relating to fermentation processes and their products. The draft materials classification guidance treats fermentation as a processing method that does not change the classification of the substrate from agricultural to non-agricultural or from non-synthetic to synthetic. Yet fermentation processes vary widely from pickling, wine-making, and cheese-making to manufacture of substances that have no apparent relationship to the substrate. Glycerin, gellan gum, and L-malic acid are examples of the last. The fact that all of these processes involve the growth of microorganisms does not seem to be sufficient to treat them the same. Therefore, we request that the Materials/GMO Subcommittee add to its workplan the development of criteria for evaluating products of fermentation processes.

CONCLUSION

The removal of synthetic glycerin from the National List will move processors towards using agriculturally derived glycerin and organic glycerin when available. **The Cornucopia Institute supports the Handling Subcommittee's recent motions to reclassify glycerin as agricultural when derived from agricultural source material and processed using biological or mechanical/physical methods described under §205.270.**

---

[2] Ibid.

Cornucopia also supports the Handling Subcommittee's motion to list glycerin, produced from agricultural source materials and processed using biological or mechanical/physical methods, at §205.606 and to take it off §205.605.

Whole Algal Flour

SUMMARY

Reject the petition to add whole algal flour to the National List of Approved Materials under §205.606.

Rationale:

- The petitioner, prior to the Fall 2014 NOSB meeting, was not able to provide enough information for the Handling Subcommittee to review the material. Due to so-called "Confidential Business Information" (CBI), the original petition had little information on the fermentation and manufacturing process and the follow-up answers were blacked out; therefore, information was insufficient to make a determination. They subsequently provided *some* material at the Fall 2014 NOSB meeting, but the documents provided were still insufficient to allow for a thorough analysis.
- It remains unknown what ancillary substances are utilized in the manufacture of this product, such as fermentation media, nutrients, antioxidants, flow agents, preservatives, or solvents. Therefore, it is also unknown what the human health impacts might be from the consumption of this product.
- There are multiple alternative substances to whole algal flour (WAF) that are organic. These include milk, cream, eggs, butter, starches, and gums.
- The Handling Subcommittee voted once again on 1/6/2015 to reject the petition, mainly because it fails the OFPA *essentiality* criteria and does not seem compatible with organic principles. The Cornucopia Institute agrees with the subcommittee's decision.

DISCUSSION

When a company petitions to add a substance to the National List under §205.606, they should supply a comprehensive explanation of why this substance is needed, how it is manufactured, and whether there are human health and environmental impacts. Unfortunately, this petitioner, Solazyme, Inc., did not do this. Any petition this incomplete should be rejected outright before it is passed onto the NOSB members, who already have a heavy workload.

Confidential Business Information

What a company considers "Confidential Business Information" should not be used as an excuse for an incomplete petition. If a company cannot provide the level of detail needed for the NOSB to make an informed decision on a product, then the manufacturer(s) should not submit a petition in the first place. Too often "proprietary and confidential" information is used as a cloak of secrecy, which should not be allowed in organics. Consumers demand transparency and The Cornucopia Institute agrees. This petition to list whole algal flour should be rejected first and foremost because of the lack of transparency about the manufacturing process. Even though the petitioner provided some additional information in their oral testimony at the Fall 2014 NOSB meeting, that was not part of the original petition and was still not sufficient to analyze this material fully.

Human health impacts

The inerts and ancillary substances used in the manufacture of whole algal flour are unknown. Furthermore, the FDA has not determined the GRAS status of this product; they have simply produced a "no further questions" document, dated 6/7/2013. The petitioner, Solazyme, Inc., has said that they assembled their own panel of experts and have "self-certified" the product to be GRAS, but that is not a legal determination.

The FDA also objected to the name of "algal flour" because it is not the common or usual name of the Chlorella species utilized. Due to a lack of information, the Handling Subcommittee was unable to establish the potential human health impacts of this product.

Alternatives exist

There are multiple organic ingredients that can provide the mouthfeel, texture, fat, and protein content that Whole Algal Flour is attempting to replace. These include animal-based products such as milk, cream, eggs, and butter. Also included are plant-based ingredients such as starches (potato, rice, etc.) and gums (guar, locust bean, xanthum, and others). Therefore, this non-organic ingredient is not necessary.

CONCLUSION

It would not make sense to replace commercially available organically produced ingredients with non-organic ones such as whole algal flour. We understand the petitioner thinks that WAF would be a good vegan alternative to animal-based ingredients, but there are already several that can be used, including potato, rice, and other plant-based starches, along with plant-based gums like guar or locust bean.

The Handling Subcommittee considered this material to be incompatible with organic principles and non-essential and voted not to list this material. **The Cornucopia Institute agrees with the subcommittee and encourages the full Board to reject the petition to list whole algal flour on the National List under §205.606**.

Triethyl Citrate

SUMMARY

Reject the petition to add triethyl citrate (TEC) to the National List for handling under §205.605(b) Non-agricultural (non-organic) Synthetic substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."

Rationale:

- Essentiality has not been demonstrated by the petitioner.
- There are a number of certified organic and natural substitute products.
- An allowed alternative substance with the same properties already exists: potassium acid tartrate (cream of tartar), listed under §205.605(b) as a synthetic allowed in processed products labeled as "organic" or "made with organic ingredient(s)."
- TEC's potential impact on the aquatic environment is unknown.

DISCUSSION

Triethyl citrate has been petitioned by Michael Foods, Inc. for use as a whipping enhancer for pasteurized egg whites during processing.[3]

Most egg products (excluding fresh shell eggs) are pasteurized in the U.S., as required by the 1970 Egg Products Inspection Act. Pasteurization of egg whites diminishes their foaming capacity resulting in reduced quality and volume of the foam itself or of the products containing whipped egg whites. TEC improves the foaming properties (stability, luster, and susceptibility to mechanical damage) of egg whites after pasteurization.[4]

This synthetic compound is listed under 21CFR 184.1911 as a Direct Food Substance Affirmed as GRAS and can be used as an ingredient in food with no limitation other than current good manufacturing practices. It is used as a flavoring agent, a solvent and carrier as well as a surfactant.[5]

TEC is also used as a pharmaceutical excipient as well as in cosmetics and has been deemed safe to use in present cosmetic practice and concentrations by the Cosmetic Ingredient Review Expert Panel.[6]

Environmental concerns

---

[3] Petition for Triethyl citrate (TEC) submitted by Michaels Foods, Inc.
[4] Technical Evaluation Report, compiled by OMRI for the USDA NOP in 2014
[5] Ibid.
[6] Ibid.

TEC has low toxicity, degrades rapidly in the soil, and is considered environmentally benign; it is used as an "environmental friendly" plasticizer and is utilized in biodegradable plastic applications.[7]

However, it seems relatively persistent in water as it is not entirely broken down by typical water treatments. Furthermore, it has been found in low amounts (ppb) in lakes, rivers, and wastewater effluents as well as in drinking water. There are currently no available studies as to the potential environmental effects of such TEC levels in the aquatic environment.[8,9]

Essentiality and alternatives

The Cornucopia Institute believes that the petition fails in its discussion of the essentiality of this compound in regard to the currently available alternatives.

Michaels Foods, Inc. states in its petition that its R&D department "***has done extensive research to find an organic substitute to serve the same purpose and has found that there is no alternative substance***."[10]

However, not only does the Technical Report (TR) list several currently available substitute substances, including some available organic, allowed natural non-organic and an allowed synthetic, it also discusses at length (lines 446-520) various alternative practices (one in use since the 18th century) that are being used to improve egg white foam stability.

Organically acceptable substitutes: Salt and sugar, either individually or in combination, can enhance foaming characteristics of egg albumen. Sugar may be the most studied and best understood agricultural product to improve foaming characteristics of heat treated egg whites. Certified organic sugar is commonly available across the marketplace, and salt is a non-organic ingredient allowed for use in organic processed food products.[11]

Guar gum is included in §205.606 as a non-organic ingredient permitted in organic products when not commercially available in organic form, but there are several sources of organic guar gum. Glycerin can also be used as an additive to enhance whipping properties of egg whites and there are several sources of organic glycerin currently available commercially.[12]

Natural (non-synthetic) and allowed synthetic substitutes: Papain enzymes can be used effectively to treat egg whites to affect their foaming capacity. They are listed under

---

[7] Ibid.
[8] Ibid.
[9] Paul E. Stackelberg, Edward T. Furlong, Michael T. Meyer, Steven D. Zaugg, Alden K. Henderson, Dori B. Reissman. Persistence of pharmaceutical compounds and other organic wastewater contaminants in a conventional drinking-water treatment plant. Science of the Total Environment 329 (2004) 99–113
[10] Petition for Triethyl citrate (TEC) submitted by Michaels Foods, Inc.
[11] Technical Evaluation Report, compiled by OMRI for the USDA NOP in 2014
[12] Ibid.

§205.605(a) as non-agricultural (non-organic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic ingredients."

Xanthan gum, guar gum (available in organic form), and carrageenan can also be used to enhance the foam stability of whipped egg white and are listed under §205.605(a)(b) and §205.606(k). However, carrageenan has been found to be a toxic substance[13] and, as such, its legal use continues to be challenged in organics.

Potassium acid tartrate (cream of tartar) is the most commonly commercially used substance to enhance egg white foaming characteristics; it is listed under §205.605(b) as a synthetic substance allowed as an organic ingredients in organic foods.[14] Based on the TR and Cornucopia's review, even its essentiality seems questionable.

CONCLUSION

The Cornucopia Institute **recommends against the listing of triethyl citrate on §205.605(b)** because it appears, based on existing industry practices, to be non-essential and its use unnecessary. Indeed, there exists a variety of sound alternative practices as well as a number of organic, allowed natural non-organic and allowed synthetic substances currently commercially available which when utilized can enhance the foaming characteristics of pasteurized egg whites. In addition, further research is needed as to the potential impact of this substance in the aquatic environment.

2016 SUNSET MATERIALS

SUMMARY

The following sunset materials are listed as discussion items:

- Egg White Lysozyme
- L-Malic Acid
- Microorganisms
- Activated Charcoal
- Peracetic Acid
- Cyclohexylamine
- Diethylaminoethanol
- Octadecylamine
- Sodium Acid Pyrophosphate
- Tetrasodium Pyrophosphate

---

13 http://www.cornucopia.org/carrageenan-2013

14 National List of Allowed and Prohibited Substances: http://www.ams.usda.gov/AMSv1.0/NOPPetitionedSubstancesDatabase

They are all due to sunset in 2016. Please see The Cornucopia Institute's review of each substance below.

DISCUSSION

Technical Reports outdated or insufficient

The Cornucopia Institute requests that technical reviews either be updated or done more thoroughly on all of these materials before they are considered for relisting. It is very challenging to properly consider these materials when many of them lack adequate and scientifically robust Technical Reports. There are several issues with the current status of the TRs:

- **Egg White Lysozyme** is included in a 2011 Technical Report on enzymes. It is given very little discussion and there is no discussion about where the egg whites come from (organic, non-organic, caged, cage-free, etc.).

- **L-Malic Acid** does not have its own Technical Review; it is only briefly mentioned in the 2003 DL-Malic Acid TAP report. This particular substance should have its own review prior to discussing its sunset.

- **Microorganisms** has a recent 2014 Technical Report that sufficiently addresses most issues concerning placement on the National List, with the exception of feedstocks and bacteriophages.

- **Activated Charcoal** has an outdated 2002 TAP report that needs more discussion of potential human health and environmental impacts.

- **Peracetic Acid** has a very outdated 2000 TAP report that should be updated. Significant new scientific research has come out on this material since that report.

- **The boiler water additives** (cyclohexylamine, diethylaminoethanol, and octadecylamine) were reviewed in a fairly thorough 2001 report but have not been reviewed since then taking into account new scientific information that could be available and whether or not ammonium hydroxide could completely replace them.

- **Sodium Acid Pyrophosphate** is included in a weak 2001 TAP review of all sodium phosphate materials.

- **Tetrasodium Pyrophosphate** had a recent 2014 review but it was very limited in scope.

It should be noted that the investigation that culminated in the publication of Cornucopia's report *The Organic Watergate*, available at www.cornucopia.org, found that some of the initial technical reviews were produced by corporate agribusiness executives or consultants, lacked scientific rigor, and included a number of unsupported conclusions. Some TRs did not include a full analysis of all published science related to specific materials.

These factors make requiring that the USDA produce accurate and impartial technical reviews at this juncture even more critical.

Egg White Lysozyme – 2016 Sunset

Oppose the relisting of egg white lysozyme on the National List §205.605.

On 1/20/15, the Handling Subcommittee voted not to remove egg white lysozyme (EWL) from the National List, voting No: 5, Yes: 0, and Absent: 3. Even though they discussed some of the public concerns about the egg whites coming from conventional eggs, one Board member felt that since EWL was so highly purified and used in limited quantities that it was "unnecessary to require an organic source." This is a justification without basis in OFPA.

DISCUSSION

Egg white lysozyme is a purified enzyme material isolated from hen egg white. The enzyme is commonly used as a preservative and an antimicrobial in cheese- and wine-making. Egg white lysozyme is used by the cheese industry to prevent butyric fermentation, also known as "late blowing," caused by *Clostridium tyrobutyricum*. Egg white lysozyme is used to stabilize wines through control of lactic acid bacteria.

Egg white lysozyme is extracted from fresh egg whites. A polymer resin is mixed with egg white where it binds to the lysozyme. The resin carrying the lysozyme is separated from the egg white. The lysozyme is removed from the resin using salts, then concentrated, purified, and dried. It is classified as "non-synthetic" according to the 2011 Technical Report, but that determination is questionable to our scientific staff based on the use of solvents.

On 9/11/06, egg white lysozyme was added to the National List under §205.605(a) Non-Synthetic, Non-Agricultural Substance, based on the NOSB's reassessment of EWL at the May 2003 meeting. The first sunset review of egg white lysozyme took place at the November 2009 meeting.[15] No comments or disagreements were presented at that time.

International regulations

[15] http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5081504

The European Food Safety Authority (EFSA) permits the use of egg white lysozyme in organic foods with labeling requirements. Scientific opinions issued by the EFSA conclude that egg white lysozyme in cheese and wine products can trigger allergic reaction in egg-sensitive individuals and, as such, "egg white lysozyme" must be listed in the ingredient label.[16]

GRAS status pending

The FDA regards egg white lysozyme as Generally Recognized As Safe (GRAS), in the tentative final ruling dated 3/13/98. In response to a 2000 petition to the FDA, no further conclusion was reached, yet the FDA states that GRAS status for the substance presumed that "egg white lysozyme" would be named as an ingredient on food packaging, due to allergen concerns.[17]

Human health concerns

Egg whites are known to be allergenic to egg-sensitive individuals. The FDA tentatively determined in the GRAS ruling that bulk and packaged foods containing lysozyme be labeled as containing "egg white lysozyme." No final conclusion has been issued; therefore, no legal requirement exists to label "egg white lysozyme" on food products in the U.S.

Two scientific opinion reports issued by the EFSA's Panel on Dietetic Products, Nutrition and Allergies (NDA), in response to a request to exempt egg white lysozyme from labeling requirements, found that levels of lysozyme present in cheese (2005) and wine (2011) products reviewed could trigger an allergic reaction in egg-allergic individuals. The European Commission requires that the words "egg white lysozyme" be listed as an ingredient when used in cheese and wine.

The 2005 EFSA opinion was reached after data submitted by the Association of Manufacturers of Natural Animal-derived Food Enzymes (AMAFE) was reviewed for potential adverse reactions when egg white lysozyme is used as a food additive. The EFSA opinion found that lysozyme in cheese could trigger an allergic reaction.[18]

The 2011 EFSA opinion reviewed the Oenological Products and Practices International Association (OENOPPIA) application to permanently exempt egg white lysozyme from labeling requirements on wine. The panel concluded that wines treated with lysozyme may trigger adverse allergic reactions in susceptible individuals.[19]

Environmental concerns

---

[16] Lysozyme in Wine: An Overview of Current and Future Applications http://onlinelibrary.wiley.com/doi/10.1111/1541-4337.12102/pdf

[17] FDA Agency Response Letter GRAS Notice No. GRN 000064. http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm153975.htm

[18] EFSA 2005. http://www.efsa.europa.eu/de/scdocs/doc/186.pdf

[19] EFSA 2011. http://www.efsa.europa.eu/en/efsajournal/doc/2386.pdf

According to a 2011 Technical Evaluation Report on enzymes, the use of organic eggs to produce lysozyme was not likely as the higher cost of organic eggs would increase the production costs.[20]

One manufacturer in Europe, Bioseutica, states that free-range hens are used for egg white lysozyme production.[21] We could not locate a manufacturer utilizing organic eggs for production of this enzyme. Therefore, the likely source of egg whites is conventional eggs from caged layers. Conventional egg production involves hundreds of thousands of birds, crammed into cages in darkly lit barns, fed conventional genetically engineered feed that also contains antibiotics and arsenic. The manure from these operations (also laced with antibiotics and arsenic) is spread onto land, eventually making its way into waterways causing pollution. None of these environmental impacts are addressed in the technical review yet they must be taken into account.

Essentiality; alternatives exist

Egg white lysozyme is known as a natural food preservative and antimicrobial. It is desirable due to its economic feasibility and low dosage required for effectiveness. The availability of organic alternatives is not known. One of the key alternatives appears to be impeccable sanitation.

Results of Cornucopia's Egg White Lysozyme Survey

In the fall of 2014, The Cornucopia Institute surveyed all certified organic cheesemakers and wine producers in the U.S. to ascertain the current usage of the 2016 sunset material, egg white lysozyme. Prior to a first-class mailing to all certified cheese and wine producers, Cornucopia sent an email to all such entities for which we had an email address. The survey results are as follows:

Cheesemakers (14 total responses): Not a single cheesemaker indicated they are using the material. A couple of cheesemakers indicated that *Clostridium* bacteria are more present in raw milk from cows fed silage. Therefore, they seek milk from cows fed fresh pasture or hay, not silage, as a way to prevent the need for EWL.

Winemakers (19 total responses): Fourteen of the winemakers indicated they never use EWL and five said they sometimes use the product.

Interestingly, several of those who said they did use egg white lysozyme were very large, nationally distributed wine brands. This could indicate that EWL is being used to control for some of the factors inherent in large volume production.

---

[20] Technical Evaluation Report. Enzymes. August 19, 2011. Compiled by ICF International. http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5094942
[21] Bioseutica. Lysozyme. http://www.bioseutica.com/products/lysozyme. Viewed 9/13/14.

Alternatives that the 14 winemakers use in order to avoid using egg white lysozyme include: SO_2 gas (which is not actually allowed for a 100% certified organic product), filtration, isinglass (fish bladder), organic egg whites, using high quality grapes that aren't already rotting, and best management practices such as impeccable sanitation. Many of these techniques were cited by respondents not using EWL.

Technical Report

In 2000, the NOSB discussed animal enzymes currently in use. A TAP review was presented that covered six enzymes but did not include lysozyme. Minutes from the November 2000 NOSB meeting show that "[t]he board decided to list 6 specific animal enzymes as allowed, without annotation. They did not include a listing for lysozyme, which does not have a final GRAS status from FDA."[22]

A 2003 TAP report was issued on "Enzymes, Plant and Fungal." In the conclusion, the reviewer states, "Finally, animal produced enzymes were not considered in this review and the NOSB may want to refer those to TAP as well, or explicitly demur."[23] **Yet egg white lysozyme was added to the National List in 2006, without even having a technical review done beforehand.**

Finally in 2011, a Technical Evaluation Report on enzymes, including egg white lysozyme, was prepared by ICF International for the USDA National Organic Program.

The report implies that it is unlikely that organic eggs are used for production but does not provide details on the source of the eggs used to produce EWL. Additionally, the report does not address the negative animal health consequences of conventional egg production, or present information on how or why the substance cannot be obtained organically in the appropriate quality or quantity. Under the evaluation question 9 on how the manufacturing of these enzymes could be harmful to the environment or to biodiversity, the report says nothing about from where the animal products were derived. Nor does it address how conventional animal production is detrimental to air, water, and soil quality. At less than 20 pages of text, **this Technical Report is inadequate to cover the potential human and environmental health implications of the manufacture and consumption of enzymes in organic production**.

While the pending GRAS status for egg white lysozyme is mentioned in the 2011 TR, **no mention of labeling for allergic reaction in egg-sensitive individuals is addressed in the TR** (as is required in Europe). Given the EFSA opinions on the possible allergic effects of egg white lysozyme for egg-sensitive individuals, the precautionary principle suggests that clarification of the labeling requirements for egg white lysozyme is needed.

---

[22] NOSB. Official Minutes November 2000. www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5057493

[23] USDA, 2003. TAP Review: Enzymes, Plant, and Fungal. NOSB/National List Comment Form: Processing.

CONCLUSION

In conclusion, The Cornucopia Institute has several concerns about egg white lysozyme. These include:

- Quality and completeness of the 2011 technical review;
- Questions about the classification as "non-synthetic";
- Allergenic concerns; need for allergen labeling;
- Conventional production; animal welfare; and
- Essentiality when it appears that organic cheesemakers don't use it and only a minority of organic winemakers do. It should be pointed out that not a single wine- or cheesemaker submitted written or oral testimony for the Fall 2014 NOSB meeting in support of this substance. If egg white lysozyme is truly essential, why the silence?

L-Malic Acid – 2016 Sunset

Oppose the relisting of L-malic acid on the National List §205.605

On 12/16/14, the Handling Subcommittee voted No: 5, Yes: 0, Absent: 3 not to remove L-malic acid from the National List. It is unclear from the brief meeting notes what the justification was to maintain this material on the list.

DISCUSSION

L-malic acid was added to the National List under §205.605 in 2006 as a non-synthetic, non-organic ingredient used in or on organic foods. The TAP review was conducted in 2003 based on the petitioner's request for DL-malic acid to be placed on the National List. The TAP review demonstrated that DL-malic acid is synthetic and did not meet OFPA criteria, but it made casual mention that L-malic acid could be produced naturally through double fermentation.

No separate petition was made for L-malic acid; therefore, **no Technical Review was written specifically for that substance. Yet it was approved for use in 2006**.

L-malic acid is primarily used as a pH adjuster in beverages. It is produced by a double fermentation process. First, glucose is fermented into fumaric acid then the fumaric acid is fermented into L-malic acid. <u>No other information about its manufacturing process is available in the TAP review</u>.

Environment and human health

The feedstock used for the original glucose and any ancillary substances used in the fermentation process are unknown. Glucose used in the food processing industry is commonly derived from corn syrup, most of which is genetically engineered.[24] Therefore, **it is likely the glucose used in the fermentation process is derived from genetically engineered corn**. This is obviously not in line with organic principles.

Essentiality

There are a few non-synthetic and, in some cases, **organic alternatives already available to adjust pH of various foods and beverages**. These include vinegar, lemon juice, lactic acid, and citric acid. They all give slightly different flavors to the foods they are combined with. In searching the ingredient list of a wide variety of organic beverages, we were only able to find one product, from Honest Tea, which contained L-malic acid. Most other manufacturers and other products use citric acid as a pH adjuster.

Not a single food processor or drink manufacturer submitted written or oral testimony in support of this material. This calls into question the essentiality of the substance.

CONCLUSION

We believe L-malic acid fails the criterion of *impacts to human health and the environment* if the glucose feedstock is derived from conventionally grown and/or GMO crops. Additionally, it fails the *essentiality* criterion because there are more acceptable alternatives, and it appears to have neither widespread use nor industry support. Likewise, without an actual Technical Review, it is impossible to evaluate this substance. **Therefore, The Cornucopia Institute recommends removing this substance from the National List.**

Microorganisms – 2016 Sunset

Support the relisting of microorganisms on the National List at §205.605 with the exception of bacteriophages.

On 1/6/15, the Handling Subcommittee voted not to remove microorganisms from the National List, voting No: 6, Yes: 0, Absent: 2. The members are in support of creating a complete chart of all the materials to clarify which materials are already on the National List and which are not.

DISCUSSION

---

[24] Hull P. 2010. Glucose syrups: Technology and applications. Wiley-Blackwell.

Microorganisms (food-grade) added to the National List under §205.605 in 2006 as a non-synthetic, non-organic ingredient used in or on organic foods include bacteria, fungi, yeasts, viruses, and bacteriophages. They are used for processing and handling of many foods, including cheeses, wines, probiotics, fermented vegetables, and many others.

Environment and human health

There are questions about what starter culture feedstocks are used (which could include conventional milk or lactose derived from conventional milk) and what inert ingredients are added to the formulated products (which could include rice flour, dextrose, and others) (TR lines 417, 439-440). Some chemicals (preservatives) may be added to protect the microorganisms from oxidation, including sodium chloride, calcium chloride, and others (TR line 461). Carriers are added, which may be organic or non-organic (dried milk, soy, wheat, etc.) (TR line 466).

Although microorganisms in food are primarily used as probiotics or for fermentation (both considered parts of a healthy diet), **one class of microorganisms is used as a biocontrol agent to prevent certain pathogens from spreading on foods.**

In our opinion, this use is very different in nature than fermentation or probiotics.

Bacteriophage viruses infect and replicate within pathogenic bacteria, such as *Salmonella* or *Listeria*, and kill them. We believe this class of microorganisms should be removed from the existing listing and instead go through a separate petition and listing process. They might very well be safe and effective in organics as alternatives to synthetic preservatives, but they merit their own, specific analysis.

Bacteriophages could be used as a band-aid post-harvest solution to contaminated meat and cheese products. Importantly, there is no information in the TR about potential human health impacts of bacteriophage viruses.

For example, bacteriophages may act as vectors of undesirable traits (e.g., virulence and antibiotic-resistance genes). Additionally, although they are fairly host specific, they could also attack beneficial bacteria such as those that reside in the human gut.[25]

CONCLUSION

We believe that the Technical Review needs to further investigate the issues of culture feedstocks, inerts, added chemicals, and carriers in order for the NOSB to consider relisting microorganisms. These are particularly troublesome issues in meeting the OFPA's environment and human health criterion.

---

[25] Garcia P, Martinez B, Obeso JM, and Rodriguez A. 2008. Bacteriophages and their application in food safety. Letters in Applied Microbiology 47(6): 479–485.

Because microorganisms are so important in the production of so many traditional and nourishing foods, we support the continued listing of them. However, **we do believe that bacteriophages should be removed from the current listing due to the lack of information about their health effects and their use as a post-harvest biocontrol substance**, which differs from the uses of other microorganisms listed. If bacteriophages are taken off the current listing, we can support the continued listing of microorganisms.

Activated Charcoal – 2016 Sunset

Support the relisting of activated charcoal on the National List §205.605.

On 12/16/14, the Handling Subcommittee not to remove activated charcoal from the National List, with No: 5, Yes: 0, and Absent: 3. They commented that this material is in widespread use, is benign, and has no ancillary substances.

DISCUSSION

Activated charcoal was added to the National List under §205.605 in 2006 as a synthetic, non-organic substance allowed as a filtering agent for organic foods/beverages and only deriving from vegetative sources. It is used to remove color, to filter out certain undesirable tastes or odors, and to filter water. The original petitioner used activated charcoal to take out color and undesirable tastes from organic white grape juice. It is unknown how many organic processors are using activated charcoal.

Environment and human health

The 2002 TAP reviewers noted some potential environmental and human health impacts from the manufacture and use of synthetic activated charcoal. These include:

- Activated charcoal can be made from agricultural (wood, vegetables, hulls) and non-agricultural sources (natural gas, burning oils, or resins). The non-agricultural sources have multiple environmental and human health impacts and should continue to be prohibited.
- Some polyphenols (antioxidants) and minerals can be removed by using activated charcoal as a filtering agent, thus degrading the nutritional quality of the product.
- Even though the listing notation calls for only activated charcoal from vegetative (agricultural) sources, the processor/buyer has little control over what charcoal sources are actually in their specific product.

Technical Review

The most recent TR for activated charcoal is dated 2002.[26] A new TR would allow for investigation of concerns over disposal of potentially hazardous waste should toxic chemicals be removed by the activated charcoal, the availability of activated charcoal processed from agricultural products that meet NOSB standards, and the compatibility of this method of filtration with organic handling standards.

CONCLUSION

It appears that there may be a few environmental and health considerations related to this material, and **the full scope of potential liabilities is unknown without a new, current Technical Review**. Not a single entity submitted written testimony in the fall of 2014 opposing this substance. Therefore, The Cornucopia Institute **supports the continued inclusion of this material on the National List**.

Peracetic Acid – 2016 Sunset

Support the relisting of peracetic acid on the National List §205.605.

On 1/27/15, the Handling Subcommittee voted No: 7, Yes: 0, Absent: 1 not to remove peracetic acid from the National List. They commented that this material is widely used and most of the comments they received about this substance were positive.

DISCUSSION

Peracetic acid was added to the National List under §205.605 in 2006 as a synthetic, non-organic substance allowed as a sanitizer on food contact surfaces and in wash/rinse water.

Environment and human health

Compared to other commonly used sanitizers in the food industry, peracetic acid may be more compatible with organic handling than the use of halogen-based sanitizers and disinfectants such as chlorine bleach, iodophors, or quaternary ammonia products. It biodegrades into harmless substances,[27] unlike chlorinated substances.

Essentiality

Hydrogen peroxide, vinegar, and citric/lactic acid can also be used as an alternative to peracetic acid for certain uses. However, research has shown that peracetic acid is more

[26] AMS. Activated Carbon. Processing. 2002 TAP Review http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5066960

[27] http://www.epa.gov/pesticides/chem_search/cleared_reviews/csr_PC-000595_12-Jul-07_a.pdf

effective than the alternatives in many situations.[28,29] Other research shows that it is important to alternate disinfectants to avoid building up resistant pathogens.[30] Thus, having several alternatives for disinfecting is important.

CONCLUSION

Because peracetic acid appears to satisfy all three criteria of OFPA, **The Cornucopia Institute recommends relisting this substance**.

Boiler Chemicals: Octadecylamine, Diethylaminoethanol, and Cyclohexylamine – 2016 Sunset

The Cornucopia Institute **opposes** the relisting of these three boiler amines (octadecylamine, diethylaminoethanol, and cyclohexylamine) on the National List §205.605.

On 12/16/14, the Handling Subcommittee voted No: 0, Yes: 5, and Absent: 3 to remove these three boiler amines from the National List. They commented that these materials fail multiple OFPA criteria and that the industry is moving away from their use.

The last TAP review was in 2001 for each additive. The Cornucopia Institute recommends that **a current TAP review be completed** in order to help the Board determine whether ammonium hydroxide could completely replace these three boiler additives up for sunset. Alternatively, a separate steam generator may be used at the point of contact in which packaging sterilization is needed, rather than using steam generated from the boilers that feed an entire facility.

Rationale:

- The TAP reviews, dated 2001, found all three substances to be highly toxic to humans through a number of modes, and the materials and their manufacturing process to be harmful to the environment.

---

[28] Bauermeister LJ, Bowers JW, Townsend JC and McKee SR. 2008. Validating the efficacy of peracetic acid mixture as an antimicrobial in poultry chillers. Journal of Food Protection 71 (6): 1119–1122.
[29] Flores MJ, Lescano MR, Brandi RJ, Cassano AE and Labas MD. 2014. A novel approach to explain the inactivation mechanism of Escherichia coli employing a commercially available peracetic acid. Water Science and Technology 69 (2): 358–363.
[30] Bore E and Langsrud S. 2005. Characterization of micro-organisms isolated from dairy industry after cleaning and fogging disinfection with alkyl amine and peracetic acid. Journal of Applied Microbiology 98 (1): 96–105.

- Many organic processors are able to turn off the boiler chemical feed prior to and during organic runs. However, these "blow-downs" dispose treated water as wastewater, increasing the use of these chemicals and environmental concerns over their disposal, thereby presenting the need for safer boiler additive alternatives.
- Handlers with entirely organic operations may still have difficulty with acid attack in the steam lines and require a volatile amine for proper maintenance. As a result, ammonium hydroxide, which was petitioned to be added to the National List as a boiler additive in 2012, is recommended as an effective "neutralizing amine" replacement for these more toxic volatile amines.

DISCUSSION

The boiler chemicals octadecylamine, diethylaminoethanol, and cyclohexylamine are currently on the National List under §205.605b for use only as boiler water additives for packaging sterilization.

Most boiler additives are used to prevent scale and can be non-volatile so they remain in the boiler water when steam is generated. However, a volatile "neutralizing amine" is required to prevent "acid attack" within steam condensate lines. Therefore, octadecylamine, diethylaminoethanol, and cyclohexylamine were added to the National List, despite their known toxicity to humans and the environment.

Diethylaminoethanol and cyclohexylamine are volatile "neutralizing amines" used to prevent "acid attack." Acid attack is a problem in steam condensate lines and "neutralizing amines" are added to pass into the steam to neutralize carbon dioxide in the condensate. Ammonium hydroxide is known to be an effective neutralizing agent as well. In order to be effective against acid attack in the steam condensate lines, a volatile amine is required so it passes over along with the steam and is present when the steam condenses to immediately neutralize the carbonic acid as it is formed**.**

Octadecylamine is a "filming amine" used to form a protective film on steam lines and condensate piping to protect from oxygen and acid attack. Filming amines are continuously injected into the steam flow leaving the boiler.

Ammonium hydroxide, although not yet approved by the NOP as a boiler additive, is also a volatile "neutralizing amine." **Ammonium hydroxide is considered GRAS, unlike the three volatile amines, and is approved as a direct food substance**. In addition, the compound formed when ammonium hydroxide reacts with carbon dioxide is ammonium carbonate, which is already on the National List.

The Handling Subcommittee brought up four items that <u>need further discussion</u>:

1. **How common is the use of these materials in organic handling operations?**

   Cornucopia's survey, conducted in Spring 2014, indicates that they are still commonly used in organic handling operations. The other boiler additives on the list, including sodium and potassium salts, are not volatile so they do not carry over in the steam and thus are ineffective at keeping steam lines clear of acid attack.

2. **Are there alternative practices or materials that would make the use of this material obsolete?**

   Yes, it appears that ammonium hydroxide is an effective alternative.[31] It also is known to be a less toxic alternative.[32, 33]

3. **Could ammonium hydroxide, if it were approved for use, serve as a possible substitute for this material?**

   Yes, our research indicates that ammonium hydroxide is a suitable substitute with a lower impact on human and environmental health.[34, 35] There are non-dairy, organic processing facilities in which ammonium hydroxide is not typically used, for example in juice bottling. In those cases, a separate steam generator may be used at the point of contact in which packaging sterilization is needed, rather than using steam generated from the boilers that feed an entire facility.

4. **Have there been any changes (increase or decline) in the use of this substance during the current sunset cycle?**

   Our survey of 19 organic processors indicated that 17 felt that boiler additives were necessary to prevent frequent system failures and even explosions. This indicated that some processors would need guidance on how to proceed without boiler additives, although some organic processors are using water filtration systems to prevent acid attack instead of volatile boiler amines.

Other concerns: The dairy industry

The FDA permits these three volatile amines in steam but "exclud[es] use of such steam in contact with milk and milk products." Octadecylamine, diethylaminoethanol, and cyclohexylamine are the only NOP-allowed volatile additives that can neutralize carbon dioxide in steam, but they are prohibited by the Pasteurized Milk Ordinance and the USDA dairy plant inspection rules.

Instead, organic dairy processors use a number of strategies to maintain boiler lines. These include stainless steel piping, extensive water treatment of the feed water, physical and

---

[31] http://www.enviroaqua.com/media/newsletters/Neutralizing%20Amines%20&%20Ammonium%20Hydroxide%20Volume%209,%20Issue%209.envaq.pdf
[32] http://www.gvsd.org/cms/lib02/PA01001045/Centricity/Domain/18/Questions%20and%20Answers%20about%20Ammonium%20Hydroxide%20use%20in%20Food%20Production.pdf
[33] http://www.accepta.com/images/product-safety-data/MSDS_Accepta%20Ltd_Accepta%202589.pdf
[34] http://www.enviroaqua.com/media/newsletters/Neutralizing%20Amines%20&%20Ammonium%20Hydroxide%20Volume%209,%20Issue%209.envaq.pdf
[35] http://www.steamforum.com/pictures/water%20treat%20Boilers%281%29.pdf

chemical deaeration, interruption of boiler water treatment prior to organic processing, "bleed runs," "blow-downs" (removal and disposal of treated boiler water as waste water), and dismantling and cleaning of the system prior to organic handling. While this demonstrates that the three volatile amines on the National List are not essential, these measures have environmental and safety concerns including shortened life of the boilers and discharge of chemicals into the waste stream.

Other concerns: Non-volatile materials that do not carry over into the steam

It is the position of Pennsylvania Certified Organic that "only materials specifically allowed on the National List at §205.605 or non-volatile materials that do not carry over into the steam are allowed." We disagree with the notion that non-volatile materials do not need to be added to the National List because organic standards are based on a whole systems approach, not just on whether or not there is chemical residue on the food.

CONCLUSION

The Cornucopia Institute **recommends the removal of octadecylamine, diethylaminoethanol, and cyclohexylamine from §205.605b and the addition of ammonium hydroxide to §205.605 for use as a boiler additive.** We conclude that this is the best solution to maintain boiler health while minimizing the impact to the environment and humans.

Sodium Acid Pyrophosphate – 2016 Sunset

Oppose the relisting of sodium acid pyrophosphate on the National List §205.605.

On 12/16/14, the Handling Subcommittee voted No: 5, Yes: 0, and Absent: 3 not to remove sodium acid pyrophosphate (SAPP) from the National List. It appears that the subcommittee considered comments by an organic certifier who had a few clients using this material and by the original petitioner. Based on the review of the subcommittee minutes members did not appear to discuss the concerns that four consumer groups put forth opposing the relisting of this material.

DISCUSSION

Sodium acid pyrophosphate is listed for use as "a leavening agent only" under §205.605(b), synthetics allowed. It was added to the National List on 9/12/06. SAPP, also known as disodium pyrophosphate, is produced through a reaction of sodium carbonate with phosphoric acid, followed by heating the resulting monosodium phosphate. It is used as an acid source to react with sodium bicarbonate. This produces a controlled release of carbon dioxide that leavens baked goods.

A TAP review for general class of materials "Sodium Phosphates," dated 9/21/01, was used for the original listing of SAPP.

Environmental concerns

The 2009 sunset review of SAPP found "environmental impact from manufacture and use is minimal."[36] Later, a 2011 a petition to expand the current listing to include sodium acid pyrophosphate as a sequestrant for vegetables (e.g., to reduce oxidation) was rejected.

A TR compiled in 2010 found that the waste from phosphoric acid, used to manufacture SAPP, is a potential threat to the environment, and unless carefully managed, "waste products can leach heavy metals into groundwater… [and] can lead to concentration of toxic heavy metals in food products."[37] In response, the NOSB (April 2011) concurred with the Handling Subcommittee criteria evaluation finding that adverse effects on environment are present in the manufacturing process of SAPP.[38]

Human health concerns

Sodium acid pyrophosphate is believed to be safe when used in food at low levels and the material is listed as GRAS for food use by the FDA.[39]

SAPP is a phosphoric salt. The U.S. Dietary Recommended Allowance suggested intake of phosphorus is 700 mg per day for adults. The tolerable upper intake level (UL) is 4,000 mg.[40] According to the FDA, and a search of scientific literature, no evidence was found that SAPP when used in the application of a leavening agent is detrimental to health.

The amount of phosphorus found in food additives is significantly lower than the levels found in high-phosphorus foods, such as milk and meat. According to the National Institutes of Health (NIH), excessive levels of phosphorus in the blood, while rare, may interfere with calcium regulation.[41]

Essentiality; alternatives exist

The 2011 sunset review final rule issued by the AMS notes a comment received in support of SAPP that stated, "[W]ithout the allowance for this substance as a leavening agent, many

---

[36] NOSB Handling Committee Recommendation 2009. http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5081509
[37] Technical Evaluation Report. September 17, 2010. Compiled by Technical Services Branch for the USDA NOP http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5088984
[38] NOSB Committee Recommendation. April 2011 http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5091720
[39] U.S. Food and Drug Administration. April 2013. Select Committee on GRAS Substances (SCOGS) Opinion: Sodium acid pyrophosphate.
[40] The National Academies. 1997. Dietary Reference Intakes for Calcium, Phosphorus, Magnesium, Vitamin D, and Fluoride.
[41] NIH. Medline. Phosphorus in the diet. September 2014.

organic baked goods would no longer be available because" a satisfactory alternative does not exist.[42] However, not a single baker or food processor wrote in support of SAPP for the Fall 2014 NOSB meeting. If it is so "essential," why the lack of support?

A non-synthetic leavening agent available is sodium bicarbonate. Synthetic alternatives include calcium phosphates and ammonium bicarbonate.

Technical Report

Discussion of the environmental concerns found in the 2010 TR prepared for the petition to use SAPP as a sequestrant should be considered in the review of SAPP under its approved use as a leavening agent.

CONCLUSION

It does not appear that conclusive evidence exists to support the relisting of this material. It appears to fail the environment and essentiality criteria. **Therefore, The Cornucopia Institute recommends removing this substance from the National List.**

Tetrasodium Pyrophosphate – 2016 Sunset

The Cornucopia Institute **opposes** the relisting of tetrasodium pyrophosphate on the National List §205.605.

On 12/2/14, the Handling Subcommittee voted Yes: 6, No: 0, and Absent: 2 to remove tetrasodium phyrophosphate (TSPP) from the National List. They based this vote on their belief that TSPP fails several OFPA criteria, including availability of alternatives, lack of essentiality, and inconsistency with organic handling.

DISCUSSION

Tetrasodium pyrophosphate was added to the National List under §205.605(b) on 9/12/06 with the notation "for use only in meat analog products." The NOSB recommended relisting of TSPP at the sunset review in November 2009.[43]

The material acts as buffer and dough conditioner in organic meat alternative products. TSPP is prepared by molecular dehydration of dibasic sodium phosphate at 500°C.

[42] National Organic Program Sunset Review 2011. http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5092398
[43] AMS Sunset of Tetrasodium pyrophosphate. 2009. http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5081510

Environmental concerns

No significant environmental concerns when TSPP is used as a food additive have been found. The 2002 TR notes a primary environmental concern is when TSPP contained in high phosphate detergents is released into water, causing algal blooms in lakes.

Human health concerns

Animal studies have found a connection between TSSP and kidney damage when high concentrations were added to the diets of rats.[44] No conclusive scientific studies on the effect of TSPP for human health when used at recommended level were found. According to the FDA, TSPP is regarded as GRAS when used "in accordance to good manufacturing practice."[45]

Essentiality; alternatives exist

Non-synthetic alternatives exist. **In the 2002 TR, a majority of reviewers concluded that TSPP is not necessary to the processing of organic foods**.

Reviewer 2, an organic consultant with extensive processing experience, states, "Numerous cookbooks and simple food processing manuals give recipes and procedures for producing seitan and other wheat gluten products." Reviewer 2 further comments, "[N]umerous cookbooks state how to do this very simply using water only."

Further, Reviewer 1 points out, "According to Internet websites, Arrowhead Mills produces a 'Seitan Quick Mix.' Also, some health food stores sell 'wet' seitan in the refrigerated section. These products apparently do not contain TSPP. Thus, it appears that seitan can be prepared without TSPP."

Other than the International Food Additives Council, not a single other entity wrote in support of relisting TSPP at the Fall 2014 NOSB meeting. This could indicate its lack of use and essentiality in the industry.

Technical Report

In the first TR, issued in 2002, all reviewers agreed that tetrasodium pyrophosphate is a **synthetically produced** food additive. **Two of the three reviewers recommended TSPP not be added to the National List**.[46] The report appears inconclusive, yet TSPP passed a full NOSB vote for listing in April 2004.

---

[44] NIH. Toxnet.
http://toxnet.nlm.nih.gov/cgi-bin/sis/search/a?dbs+hsdb:@term+@DOCNO+854
[45] FDA. PART 182. Substances Generally Recognized as Safe.
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=182.6789
[46] Tetrasodium Pyrophosphate. TR 2002. Compiled by Organic Materials Review Institute.
http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5105016

This vote illustrates why, in Cornucopia's *Organic Watergate* report, we were so adamant that, going forward, full Technical Reviews need to be performed for each material being considered for relisting at sunset.

In some cases, there was overt bias in the preparation of the original TAP reviews. In other cases, including possibly this one, undue influence by corporate agribusiness, including from individuals inappropriately and/or illegally appointed to the Board, quite possibly led to a number of materials that would not be listed if initially petitioned today.

In 2014, the NOSB requested a limited scope TR on TSPP for use in the 2016 sunset review. The purpose was to cover new developments in meat analogs production. Meat analogs include products that simulate the taste, texture, flavor, and appearance of specific types of meat, commonly made from ingredients other than meat.

The scope of the 2014 TR was limited to evaluation questions 11, 12 and 13. It provides **extensive information on alternative methods (question 11) to produce analog meats without TSPP**.[47] Additionally, the review describes **many natural non-synthetic substances (question 12) and organic products (question 13) available that may be used in place of TSPP**.

In response to question 11 (alternative methods) the TR states, "A variety of palatable meat analog products are now available in the marketplace (Egbert and Borders, 2000). Many of them are produced without the use of tetrasodium pyrophosphate (TSPP)."

In regards to substances that may be used in place of TSPP, the TR notes that one use of TSPP in meat analogs is to accelerate gelation, yet gel formation of many of such products is achieved through the use of other sources, such as fish, soy, pea, milk, and fungi.

CONCLUSION

Due to potential human health concerns and the availability of alternatives, it does not appear that TSPP passes the OFPA criteria to remain on the National List. **Therefore, The Cornucopia Institute recommends removing this substance from the National List.**

---

[47] Tetrasodium Pyrophosphate. TR 2014. Compiled by USDA, AMS, Agricultural Analytics Division. http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5108712

2017 SUNSET MATERIALS

Chlorine Materials – 2017 Sunset

SUMMARY

The Cornucopia Institute **remains neutral in the relisting of all chlorine materials at §205.601, 603, and 605**, specifically **calcium hypochlorite, sodium hypochlorite, and chlorine dioxide** for use as algicides, disinfectants, and sanitizers, 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.[48]

We feel the NOSB and NOP should 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.

[48] 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	• ClO2 • 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 & less corrosive than chlorine[49] • The application of chlorine dioxide does not produce halogenated DBPs (like THMs) and produces only a small amount of total organic halides (TOX)[50,51]

---

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

[50] 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.[52] • 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 trihalomethanes (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 trihalomethanes (THMs) • Less effective in alkaline waters or water contaminated with high organic material loads	• Less effective than ozone[53] • 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

[51] 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.

[52] 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.

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

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.
(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.[54]

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.[55]

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

[54] http://en.wikipedia.org/wiki/Halogen
[55] http://en.wikipedia.org/wiki/Chlorine

hypochlorite ion [OCl]; also referred to as free residual chlorine [FRC]) and combined available chlorine (CAC; organic and inorganic chloramines [NH_2Cl, $NHCl_2$, and NCl_3] or N-chloramides).[56]

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 (CaCl2O2) and sodium hypochlorite (ClNaO) are both known as bleach and have similar properties. Their minor differences are explained in the above table 1. 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.[57] 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 (ClO2) 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.[58] It also is used as a bleaching agent in paper and textile manufacturing, as a food disinfectant (e.g., for fruit, vegetables, meat, and

---

[56] 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

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

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

poultry), for disinfecting food processing equipment, and treating medical wastes, among other uses.[59]

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.**[60] 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.[61]

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, 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

---

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

reaction product of chlorine dioxide, can cause oxidative damage to red blood cells.[62] "Off gassing" by activating dilute aqueous solutions of sodium chlorite with an acid to produce chlorine dioxide can be a safety hazard to users.

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.

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 are hypochlorite ions. When mixed with organic materials (e.g., dirt), hypochlorite produces trihalomethanes (THMs), which are **carcinogenic**. Currently, the maximum contaminant level (MCL) for total THMs is 0.080 mg/L (EPA, 2009).

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 trihalomethanes (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 bioaccumulative and yet when chlorine products react with other minerals or organic matter, they produce <u>persistent organic pollutants</u>. In addition (not mentioned in the TR) mercury cell electrolysis (a common production method) of**

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

chlorine is also a huge contributor to mercury pollution—some estimates rank it as high as coal-fired power plants.[63]

Although sodium and calcium hypochlorite are low in toxicity to avian wildlife, they are highly toxic to freshwater fish and invertebrates. Even though 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). The question is, how can livestock producers ensure that only the allowed concentrations of chlorine compounds are in the wastewater/run-off 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 trihalomethanes (THM) in their urine due to their exposure to disinfection byproducts (DBPs) from washing dishes, mopping, and toilet cleaning with chlorinated substances.[64] 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.[65] 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.[66] In general, there is considerably more scientific evidence that chlorinated compounds produce toxic DBPs that are human and livestock health concerns. **The TRs**

---

[63] 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

[64] 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.

[65] 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

[66] 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.

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).

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.[67]

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

[67] 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.

- It has the identical formulation as the one identified in the DfE application reviewed by EPA.[68]

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 formulations and "inert" ingredients must also meet the DfE standard for safer cleaning products.[69] **<u>All of the approved DfE disinfectant active ingredients are on the National List</u>.** 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.[70]

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.[71]

Preliminary results of Cornucopia's Certified Organic Livestock Producer Survey

In our latest survey of certified organic livestock producers, 39% said that they used sodium hypochlorite on occasion to disinfect equipment and just one producer (out of 28 respondents to date) said they utilized chlorine dioxide. No one 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.[72]

---

[68] http://www.epa.gov/pesticides/regulating/labels/design-dfe-pilot.html
[69] http://www.epa.gov/dfe/pubs/projects/formulat/dfe_criteria_for_cleaning_products_10_09.pdf
[70] Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008. http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf
[71] 2011 Crops TR and 2006 Livestock TR.
[72] 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.[73]

Crops Subcommittee discussions

On 3/7/11, 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.

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 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.

Magnesium Stearate – Sunset 2017

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

[73] 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

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.[74, 75] Soaps are readily metabolized in the soil environment,[76] and due to magnesium stearate's insolubility in water, this substance is not bioavailable and thus poses virtually no threats to aquatic environments.[77]

The Handling Subcommittee notes dated 01/27/2015 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.

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

[74] EPA RED 1992
[75] 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.
[76] EPA RED 1992
[77] 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

properties help these tablets hold together and break apart properly.[78,79] There are no known effective alternatives that are economically viable at this time.[80]

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.[81] 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)[82], 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.[83]

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.[84, 85]

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.[86, 87]

---

78 http://www.nowfoods.com/Quality/Do-Supplements-Work/M093528.htm

79 Ibid.

80 http://www.tabletscapsules.com/Back-Page/Eliminating-magnesium-stearate-from-tablets/?ID=4

81 FDA's SCOGS Database; Report No. 60; ID Code: 557-04-0; Year: 1979

82 http://www.nowfoods.com/Quality/Do-Supplements-Work/M093528.htm

83 http://ndb.nal.usda.gov/ndb/nutrients/index

84 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

85 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

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

87 http://www.gmo-compass.org/eng/agri_biotechnology/gmo_planting/342.genetically_modified_soybean_global_area_under_cultivation.html

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.[88]

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.[89]

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.[90]

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.[91]

---

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

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

90 Ibid.

91 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 TAP review of magnesium stearate was conducted in 1995 (2 reviewers), which provided none of the information needed 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.

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.

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[92], 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.

[92] 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[93]	Sufficient Supply of Organic Alternatives Exist?[94, 95, 96, 97, 98]
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.[99] The U.S. FDA routinely monitors for pesticides residues on fruits and vegetables to ensure that food products

---

93 http://www.beyondpesticides.org/organicfood/conscience/navigation.php .
94 http://www.fruitjuiceconcentrate.org/our-products
95 http://naturesflavors.com/ingredients/juice-concentrates/organic-juice-concentrates
96 http://www.cascadianfarm.com/products/juice-concentrates
97 http://www.sunopta.com/fruits/juice-concentrates.aspx
98 http://www.lakewoodjuices.com/products
99 Colors – 2015 TR, pp 689-690

(domestic or imported) comply with pesticide tolerance.[100] 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.[101]

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.[102]

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 …"***[103]

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 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.[104] Therefore, the high pigment concentration in concentrated juice or vegetable extracts would likely create a significant interference and thus challenge to the analysis of

---

[100] U.S. EPA. 2014. Pesticide Tolerances. Office of Pesticide Programs, U.S. Environmental Protection Agency. Available: http://www.epa.gov/pesticides/regulating/tolerances.htm
[101] Colors – 2015 TR, pp 704-706
[102] http://www.beyondpesticides.org/organicfood/conscience/index.php?pid=610
[103] 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
[104] http://www.sciencedirect.com/science/article/pii/S0021967303005399

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.[105]

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,[106, 107] 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.[108],[109],[110],[111],[112] 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.

---

105 http://naturesflavors.com/baking/organic-baking/organic-food-colors
106 http://www.ers.usda.gov/data-products/chart-gallery/detail.aspx?chartId=35003
107 https://www.ota.com/what-ota-does/market-analysis
108 http://www.fruitjuiceconcentrate.org/our-products
109 http://naturesflavors.com/ingredients/juice-concentrates/organic-juice-concentrates
110 http://www.cascadianfarm.com/products/juice-concentrates
111 http://www.sunopta.com/fruits/juice-concentrates.aspx
112 http://www.lakewoodjuices.com/products

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 colors from §205.606(d).

Lecithin, de-oiled – Sunset 2017

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[113], 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.[114] How much of the non-GMO soybeans are GMO-contaminated 11 years later?
- Non-organic liquid lecithin is extracted with hexane, a dangerous solvent[115], and is de-oiled with acetone another potent and toxic solvent.[116]
- 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

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

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

[115] 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).

[116] 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).

Lecithin has a long and controversial history as a processing ingredient for use in organic food.[117]

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 alternative for "bleached lecithin in dry, de-oiled form." Accordingly, the Board 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 TR was requested and became available in 2009. This TR 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**[118] 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**:

---

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

[118] Lecithin – Organic Evolution. A NOSB presentation by Lynn Clarkson, Clarkson Soy Products. May 5, 2009

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.[119]

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 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.

CONCLUSION

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

Waxes, non-synthetic – Sunset 2017

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	-Low oxygen and CO_2 permeability, moderately resistant to water vapor. -Shiniest coating; water	-Low oxygen and CO_2 permeability. Can cause low oxygen and excessive accumulation of CO_2 leading to

[119] http://clarksonsoy.com/organic-lecithins/

	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).	insoluble, UV-resistant. -Prevents some type of post-harvest decay by supporting populations of bio-control organisms[120] **-There are commercially available shellac-based fruit coating products in which the shellac is combined only with substances permitted by organic regulations.[121,122]**	fermentation and off-flavors.[123] -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 waxes, and ancillary substances).**	-Low oxygen and moisture permeability, but more permeable to O_2 and CO_2 than shellac or wood rosin.[124] -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.[125]**	-Not as shiny coating. -Often formulated with other waxes such as shellac, wood rosin, beeswax, and candelilla for best performance.
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	-Low oxygen and CO_2 permeability, moderately resistant moisture. -Shiny coating. Delay or prevent decay of coated fruits.***** **-Currently there are no known commercially**	-Limited resistance to water vapor. -Low oxygen permeability can cause low oxygen and excessive accumulation of CO_2 leading to fermentation and off-flavors.[127]

[120] 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.
[121] OMRI. *OMRI Products Database.* Edited by Organic Materials Review Institute. Eugene, October 22, 2013.
[122] 2014 TR – Orange shellac. Page 5, lines 181-183
[123] 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
[124] Hagenmaier, R. D., and P. E. Shaw. "Gas Permeability of Fruit Coating Waxes." *Journal of the American Society for Horticultural Science*, 1992: 105-109.
[125] OMRI. *OMRI Products Database.* Edited by Organic Materials Review Institute. Eugene, October 22, 2013.

	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).	**available wood rosin-based fruit coating products in which the rosin is combined only with substances permitted by organic regulations.**[126]	-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 – Sunset 2017

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.[128] **Morpholine, an emulsifier commonly utilized in shellac-based coatings, is a known precursor of N-nitrosomorpholine, a carcinogen.**[129] **It is not allowed as an ingredient of wax coating for fruits in the European Union.**[130]

There are commercially available shellac-based fruit coating products in which the shellac is combined only with substances permitted by organic regulations.[131,132]

Rationale:

- Orange shellac, unbleached is a natural bio-adhesive polymer produced by the lac insect.

---

[127] 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
[126] 2014 TR – Wood rosin. Page 4, lines 155-157
[128] 2014 TR – Orange shellac. Page 4-5, lines 159-173
[129] Morpholine. Scientific Analysis Laboratories LTD
[130] http://nwhort.org/?s=Morpholine
[131] OMRI. *OMRI Products Database.* Edited by Organic Materials Review Institute. Eugene, October 22, 2013.
[132] 2014 TR – Orange shellac. Page 5, lines 181-183

- 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.[133]
- **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.[134,135]

Environmental health

There are no major environmental consequences associated with the production and processing of shellac.[136]

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.

---

[133] 2014 TR – Orange shellac. Page11, lines 427-428
[134] http://www.webmd.com/vitamins-supplements/ingredientmono-90-shellac.aspx?activeingredientid=90&activeingredientname=shellac
[135] Mary Ann Liebert Publication. "Final Report on the Safety Assessment of Shellac." Journal of the American College of Toxicology, 1986: 309-327.
[136] 2014 TR – Wood rosin. Page 4, lines 155-157

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.[137]

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.'*"[138] **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 competitive advantage to locally produced and marketed organic produce (which, for many cultivars, are generally sold uncoated).

---

[137] 2014 TR – Orange shellac. Page11-12, lines 472-475

[138] http://www.fda.gov/food/resourcesforyou/consumers/ucm114299, bottom of page.

Both the 2014 TR and the 2002 TAP mention a large number of possible ancillary substances, including the potentially toxic **morpholine**.[139] **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 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 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.**

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 – Sunset 2017

SUMMARY

The Cornucopia Institute **remains neutral as to the relisting of wood rosin** 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 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.[140] **Morpholine, an emulsifier commonly utilized in shellac-based coatings, is a known precursor of N-**

[139] 2014 TR – Orange shellac. Page 4-5, lines 159-173
[140] 2014 TR – Wood rosin. Page 4, lines 146-155

nitrosomorpholine, a carcinogen.[141] **It is not allowed as an ingredient of wax coating for fruits in the European Union.**[142]

Rationale:

- Wood rosin is a resin derivative obtained from two species of pine trees.[143]
- As a non-toxic natural resin, wood rosin is used in organic processing and handling almost exclusively as an ingredient in fruit wax coatings.[144, 145]
- Few effective alternatives exist besides the other non-synthetic waxes for enhancing appearance and preventing weight loss, the main functions provided by fruit waxes.[146]
- **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.**[147]

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.[148] There is no documented incidence of dermatitis due to consuming or handling wood rosin-based fruit waxes.[149]

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**

---

141 Morpholine. Scientific Analysis Laboratories LTD
142 http://nwhort.org/?s=Morpholine
143 2014 TR – Wood rosin. Page 2, lines 50-53
144 2014 TR – Wood rosin. Page 10, lines 462-470
145 2014 TR – Wood rosin. Page 4, lines 172-173
146 2014 TR – Wood rosin. Page 10, lines 477-478
147 Wood rosin. Page 4, lines 146-155
148 2014 TR – Wood rosin. Page 9, lines 429-431
149 2014 TR – Wood rosin. Page 9, lines 443-444

relatively toxic solvent classified by the EPA as a group D substance with no data as to human carcinogenicity.[150] 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.[151] 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.

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.[152]

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.[153]

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.

---

150 http://www.epa.gov/ttnatw01/hlthef/methyl-k.html
151 2014 TR – Wood rosin. Page 9, lines 405-408
152 2014 TR – Wood rosin. Page 11, lines 510-514
153 2014 TR – Orange shellac. Page11-12, lines 472-475

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.*"[154] **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 mention a large number of possible ancillary substances, including the potentially toxic **morpholine.**[155] **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 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 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.[156]

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.**

---

[154] http://www.fda.gov/food/resourcesforyou/consumers/ucm114299, bottom of page.
[155] 2014 TR – Orange shellac. Page 4-5, lines 159-173
[156] 2014 TR – Wood rosin. Page 4, lines 157-165

<u>Carnauba Wax – Sunset 2017</u>

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.[157] **Morpholine, an emulsifier commonly utilized in shellac-based coatings, is a known precursor of N-nitrosomorpholine, a <u>carcinogen</u>.**[158] **It is not allowed as an ingredient of wax coating for fruits in the European Union.**[159]

Rationale:

- Carnauba wax is a natural wax obtained from the carnauba palm.[160]
- 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.[161]
- It is allowed for organic handling and processing by the prevalent organic standards (U.S., EU, Canada, JAS, and IFOAM).
- 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.[162], [163]
- **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.**[164]

DISCUSSION

---

157 2014 TR – Wood rosin. Page 4, lines 146-155
158 Morpholine. Scientific Analysis Laboratories LTD
159 http://nwhort.org/?s=Morpholine
160 2014 TR – Carnauba wax. Page 1, lines 33-35
161 2014 TR – Carnauba wax. Page 2, lines 65-66
162 2014 TR – Wood rosin. Page 10, lines 477-478
163 2014 TR – Carnauba wax. Page 3, lines 110-112
164 2014 TR – Carnauba wax. Page 4, lines 149-167

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.[165]

Environmental health

There are no reported environmental impacts due to the production of the carnauba wax.[166]

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.

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.[167]

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

---

[165] 2014 TR – Carnauba wax. Page 10-11, lines 467-500
[166] 2014 TR – Carnauba wax. Page 9-10, lines 437-461
[167] 2014 TR – Carnauba wax. Page 12, lines 559-563

that alternatives exist that adequately match the desirable characteristics imparted by waxes and resins.[168]

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.*"[169] **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**.[170] **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 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.**

---

[168] 2014 TR – Orange shellac. Page11-12, lines 472-475
[169] http://www.fda.gov/food/resourcesforyou/consumers/ucm114299, bottom of page.
[170] 2014 TR – Carnauba wax. Page 4, lines 158-163

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.[171] In its Sunset 2017 Review summary, the NOSB requested comments pertaining to this potential reclassification.[172]

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. See below.

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.**

---

[171] 2014 TR – Carnauba wax. Page 8, lines 338-34

[172] http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5110822

CROPS SUBCOMMITTEE

PROPOSALS

Exhaust Gas

SUMMARY

The Cornucopia Institute recommends **rejecting** the petition to add exhaust gas as an allowed synthetic substance to §205.601 for underground rodent control because it fails all three OFPA criteria.

Rationale:

- Trapping is an effective method of rodent control.
- Alternative practices are already available on the National List. Vitamin D_3 is currently listed on §205.601 for use in control of burrowing rodents.
- Exhaust gas causes likely harm to non-target species, including those listed as endangered species.
- This technology contributes to greenhouse gases by unnecessary use of fossil fuels.

DISCUSSION

The petitioner, H&M Gopher Control, uses their patented PERC technology (Pressurized Exhaust Rodent Controller) to capture pure exhaust off a gasoline-fueled, internal combustion engine, then pressurize the gas and inject it into rodent burrows. The rodent tunnel system is, purportedly, immediately engulfed in a high concentration of carbon monoxide (CO) gas with the rodents reportedly killed before they escape the burrow. Kohler Co. engines are exclusively used to power the H&M Gopher Control equipment.

Exhaust gas consists of mostly water vapor (roughly 98%), nitrogen gas (N_2) and carbon dioxide (CO_2). A small portion (roughly 2%) is composed of toxic carbon monoxide gas (CO), hydrocarbons, nitrogen oxides (NOx), and sulfur dioxide (SO_2). Exhaust gas is produced in internal combustion engines, including those of tractors and other farm equipment. Conventional farm operations have utilized exhaust gas as a poison for the control of burrowing rodents for decades.

The petitioner, H&M gopher holds a patent on a system that injects pressurized exhaust gas into burrows through an air hose (see photo above[173]). The pressurized exhaust gas essentially replaces air in burrows with toxic levels of carbon monoxide, and impairs the oxygen carrying capacity of the rodents' blood.

Technical Report

A Technical Review completed in October 2014 for exhaust gas found "no historic uses of exhaust gas or carbon monoxide in organic production." However, the TR mentioned research that is currently being conducted on systems to infuse exhaust gas from machinery into agricultural soils to stimulate the metabolism of soil-dwelling microrganisms and enhance productivity of fields. These systems may be compatible with organic agriculture given their benefits to the environment by capturing exhaust emissions and enhancing soil fertility.[174, 175]

The TR notes that **exhaust gas, or carbon monoxide, is not permitted for rodent control by most international organizations**, which recommend alternative methods, such as natural repellents and traps.

Alternatives exist

Several natural alternatives to burrow fumigation exist. Most organic farmers rely on trapping to control rodents. Although not completely effective, natural barriers, reduction of hospitable habitat, encouraging natural predators, and flooding of burrows are other practices utilized. For example, in California, nesting boxes installed in farms, ranches, and vineyards are used to attract barn owls that prey on gophers and other rodents.[176]

Currently, the only synthetic substance approved under §205.601 of the National List as a rodenticide is Vitamin D_3 (cholecalciferol), but this can only be used after other methods of rodent control have been exhausted.[177] Vitamin D_3 is a poison that can carry over to predators causing them harm. Operators must document alternative methods in their Organic System Plan. Previously, sulfur dioxide (smoke bombs) were approved for use for underground rodent control, but removed by the NOSB in a 2011 sunset review.[178]

---

[173] http://hmgophercontrol.com/

[174] Boy JAW, Soriano NU, Lewis G. 2012. Bio-AgtiveTM Emissions Technology Final Report Spring 2012. Montana State University Bio-Energy Center.

[175] Heard G. 2013. Exhausted soils thriving. The Land. FarmOnLine Home. http://www.theland.com.au/news/agriculture/cropping/general-news/exhausted-soils-thriving/2676097.aspx.

[176] http://www.hungryowl.org/nesting_boxes/nontoxic.html and http://www.sfgate.com/homeandgarden/article/Barn-owls-all-too-happy-to-be-your-rat-catchers-2501173.php

[177] http://www.ecfr.gov/cgi-bin/textidx?c=ecfr&sid=6f623e1de5457587ccdfec12bc34ed1c&rgn=div5&view=text&node=7:3.1.1.9.32&idno=7#se7.3.205_1206

[178] USDA. 2011b. 2012 Sunset Review of Sulfur Dioxide listed on §205.601 Synthetic substances allowed for use in organic crop production: (g) As rodenticides (1) Sulfur dioxide—underground rodent control only (smoke bombs). http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5091715&acct=nosb

Environmental concerns

Exhaust gas can kill non-target species that cohabit in rodent burrows, which includes several endangered species in the West, such as the San Joaquin kit fox, western burrowing owl, Alameda whipsnake, California red-legged frog, San Francisco garter snake, California tiger salamander, and others. All burrow fumigants, including exhaust gas, are highly toxic to non-target wildlife. Before fumigation is used, burrows should be checked for signs of non-target animals and not treated where such wildlife is present.[179]

Another concern is that fumigation with exhaust gas and the resulting oxygen deprivation may not be effective at killing quickly, but would still be toxic, resulting in a less than humane death for non-target, and targeted, species. The TR does not provide sufficient published data on how exhaust gases might be adsorbed or affect soil microorganisms.[180]

Human health concerns

Carbon monoxide, when inhaled, can produce multiple symptoms and even death, depending on type, dosage, and length of exposure.[181] The TR provides a thorough discussion on the variety of toxic effects of exhaust gas to humans, and notes that since the exhaust gas is to be applied underground, it is likely to dissipate in the burrow soil or the outdoor air.

The manufacturers of the PERC system note that problems can occur if the probe is not in the burrow after insertion. This message of warning is posted on H&M Manufacturing's website: "If the probe is not in the burrow after insertion, the pressurized gas will blow back up the hole made by inserting the probe. This can and usually will result in sand and dirt being blown into the face of the operator. For this reason, it is strongly recommended that the operator wear eye protection. Remember, the gas is under pressure!"[182]

Humans are likely to be exposed to equal or greater amounts of carbon monoxide from routine operation of farm vehicles and equipment. The device used to produce the exhaust gas is meant for outdoor operation; still, precautions must be taken to protect workers from accidental inhalation of the exhaust gas to avoid carbon monoxide poisoning.

Crops Subcommittee discussion and vote

On 12/16/14, Crops Subcommittee members voted on the addition of exhaust gas to §205.601 as follows: Yes: 0, No: 5, Abstain: 0, Absent: 2, Recuse: 0.

---

[179] http://agr.mt.gov/agr/Programs/PestMgt/VertebratePest/Bulletins/pdf/ControllingBurrowFumigants.PDF and http://icwdm.org/handbook/rodents/PrarieDogs.asp
[180] http://countryfolks.com/organic-standards-and-rodent-control/
[181] http://ephtracking.cdc.gov/showCoRisk.action
[182] http://hmgophercontrol.com/index.php/how-it-works

CONCLUSION

The Cornucopia Institute recommends **rejecting** the petition to add exhaust gas as an allowed synthetic substance to §205.601 for underground rodent control because it fails all three OFPA criteria. Alternative effective practices including trapping are safe and effective and less likely harm to non-target species, including listed endangered species that reside in rodent burrows.

Calcium Sulfate

SUMMARY

The Cornucopia Institute recommends **rejecting** the petition to add synthetic calcium sulfate at §205.601 because it fails the OFPA criteria for essentiality and compatibility. There is abundant non-synthetic gypsum available. In addition, testing would be required to determine whether a particular batch of synthetic gypsum contains toxic contaminants.

Rationale:

- Synthetic calcium sulfate is not necessary. According to the Crops Subcommittee checklist, there is abundant non-synthetic gypsum available, as well as other sources of calcium and sulfur.
- The Crops Subcommittee cites a study by the Electric Power Research Institute that lists 29 contaminants, mostly heavy metals that may be found in flue gas desulfurization gypsum.
- The EPA recommends that a chemical analysis be done to support a decision to use synthetic gypsum. This would put a burden on certifiers, materials review organizations, and growers to ensure that the gypsum will not contaminate the soil.
- **There is no Technical Report for this substance.**

DISCUSSION

A petition has been submitted by the American Coal Ash Association to add synthetic calcium sulfate (also known as "FGD gypsum") under §205.601 as an allowable synthetic substance for organic crop production. As explained in the petition, the synthetic form of calcium sulfate is a product of flue gas desulfurization (FGD) equipment used at coal-fired power plants to control sulfur dioxide emissions. The FGD process produces a solid that can be either dry or a slurry form.

Synthetic calcium sulfate can be used as an agricultural soil amendment to improve the physical properties of heavy clay or sodic soils. It increases water infiltration, decreases soil erosion and nutrient build up in waterways, facilitates no-till practices, and can improve nutrient uptake for some crops. [183]

Technical Report

No TR has been requested for synthetic calcium sulfate. While similar in composition to mined calcium sulfate, FGD calcium sulfate is currently disposed of in landfills. A recent review of nine research studies on uses of FGD gypsum (calcium sulfate) for agricultural uses found knowledge gaps and a need for further research.[184]

A study by the Electric Power Research Institute found the following elements in FGD gypsum in varying concentrations: aluminum, arsenic, boron, barium, beryllium, calcium, cadmium, cobalt, chromium, copper, iron, mercury, potassium, lithium, magnesium, manganese, molybdenum, sodium, nickel, phosphorus, lead, sulfur, tin, selenium, silicon, strontium, titanium, vanadium, and zinc.[185]

Alternatives exist

While non-synthetic calcium sulfate is allowed for organic agriculture, the petitioned request is for what is commonly known as "FGD gypsum," a synthetic form of calcium sulfate. The overriding claim the petitioner makes for the necessity of synthetic calcium sulfate is increased availability stating "for the production or handling of an organic product by those organic farmers who have barriers to acquisition and/or use of natural gypsum but have no barriers to acquisition and/or use of FGD gypsum." The petition later states that more than 35 brands of natural, mined gypsum (calcium sulfate) are approved for organic use.

In a 2014 scientific review of FGD calcium sulfate studies for agricultural use, the authors found that FGD calcium sulfate may be a low-cost alternative to mined calcium sulfate, yet called for further research to evaluate crop production, management practices, and environmental effects of FGD gypsum.[186]

Other non-synthetic substances can easily substitute for gypsum if necessary, including limestone, bone meal, and elemental sulfur, as well as organic matter from compost or cover cropping.

Essentiality

Synthetic calcium sulfate is not essential to organic crop production. Non-synthetic substances, for example mined calcium sulfate, are available for soil clay and sodic soil

---

[183] http://greenleafadvisors.net/wp-content/uploads/2014/01/Gypsum-Literature-Final-11-12-2013-DP.pdf
[184] https://dl.sciencesocieties.org/publications/jeq/abstracts/43/1/246
[185] Electric Power Research Institute, 2011. Composition and Leaching of FGD Gypsum and Mined Gypsum. (p.A-1, 2; p.33-34)
http://www.epri.com/abstracts/Pages/ProductAbstract.aspx?ProductId=000000000001022146
[186] https://dl.sciencesocieties.org/publications/jeq/abstracts/43/1/246

amendment. The petitioner states synthetic calcium sulfate is more economical and may be more available than mined calcium sulfate. This does not make the substance essential for organic crop production.

Other practices for maintenance of soil health in organic production include crop rotation, cover crops, organic mulches and compost, and allowable synthetic soil amendments included NOP listing.

Environmental concerns

A recent study found that while FGD calcium sulfate (synthetic gypsum) appears to have little environmental risk, more information is needed to evaluate the risks associated with the introduction of trace elements to the environment such as mercury (Hg) and arsenic (As) and recommended that management practices for use across a range of soils, cropping systems, and climates be established.[187] A scientific review includes a table that lists 11 "knowledge gaps" recommended for further research. Two of the recommendations appear to specifically address environmental concerns:

- "Continued environmental monitoring to ensure the gypsum used does not load heavy metals in soil."
- "The impacts for reducing soluble P movement from fields to vulnerable water bodies."

An EPA fact sheet on FGD gypsum states, "[T]he amount and types of trace materials and unreacted sorbents found in the gypsum can vary among power plants and among mines. If you are considering using FGD gypsum products as a soil amendment, it is appropriate that the chemical analysis of the material be provided by all commercial sources to support decision-making in their use, as States may have regulations and standards that need to be followed."[188]

Human health concerns

A toxicology study on both mined and synthetic calcium sulfate suggests the materials have little, or no, effect on human health. The substances are potential irritants to the eyes and respiratory system. Proper handling procedures are recommended.[189] Concerns over health risks associated with trace heavy metals in synthetic calcium sulfate, such as arsenic and mercury, accumulating in our drinking water and bioaccumulating in fisheries that humans consume has not been well studied.

Crops Subcommittee action

---

187 http://www.sciencedirect.com/science/article/pii/B9780123876898000059
188 EPA factsheet, Agricultural Uses for Flue Gas Desulfurization (FGD) Gypsum. http://nepis.epa.gov/Exe/ZyPDF.cgi/P1001II9.PDF?Dockey=P1001II9.PDF
189 http://ntp.niehs.nih.gov/ntp/htdocs/chem_background/pubnomsupport/gypsum1_508.pdf

The Crops Subcommittee expressed the sentiment that calcium sulfate is not essential for organic farming due to the many alternatives to synthetic gypsum and voted against its listing. It was felt that non-essentiality outweighs the recycling benefits associated with the use of FGL gypsum.

Listing Motion: Motion to add calcium sulfate, produced by the flue gas desulfurization (SGD) process as petitioned to §205.601 Motion by: Zea Sonnabend. Seconded by: Harold Austin Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

CONCLUSION

Since synthetic calcium sulfate does not meet OFPA criteria and abundant natural gypsum exists, we support the Crops Subcommittee proposal to **deny the petition to list synthetic Calcium Sulfate**.

3-decene-2-one

SUMMARY

The Cornucopia Institute **opposes** the petition to add 3-decene-2-one because it fails all three of OFPA's criterion for inclusion on the National List: potential negative impacts on human health and the environment, compatibility with organic practices, and essentiality. Effective, naturally derived organic alternatives exist.

Rationale:

- There is no TR for this material.
- There is insufficient information for both health and environmental concerns.
- Alternatives exist, including ethylene and naturally derived clove oil.

DISCUSSION

3-decen-2-one (3D2) is a biochemical pesticide that belongs to the chemical family of the alpha-beta unsaturated aliphatic ketones, used as a plant growth regulator to inhibit post-harvest sprouts on storage potatoes. The function of 3D2 is to destroy the meristem of sprouting potato tubers and surrounding sprout tissues.[190] 3D2 is applied through the use of thermal fogging of the harvested potato crop while in storage.

[190] 3-decene-1-two Fact Sheet EPA. http://www.epa.gov/pesticides/chem_search/reg_actions/pending/fs_PC-068403_15-Mar-13.pdf

The petitioner, AMVAC, has requested the addition of this synthetic pesticide to §205.601 for post-harvest use in potatoes. The substance was approved for commercial use as a potato sprout inhibitor in the United States in 2013, under the trademark SmartBlock. In their petition, AMVAC states use of 3-decene-2-one results in prevention of sprouts for one to three months depending on type of potato and storage conditions.[191]

Technical Evaluation Report

The Cornucopia Institute requests that a sufficient Technical Evaluation Report (TR) be completed for every material before consideration for listing. No TR has been requested for 3D2 though this biochemical pesticide has been in use since it was registered with the EPA in 2013. The 1/6/15 meeting of the Crops Subcommittee review for 3-decene-2-one states the "petition found sufficient" and that no TR was requested.[192] How can a petition be found, by this lay panel, to be sufficient if there is no independent analysis of the substance through a TR?

Alternatives exist

Alternative, organic methods for inhibiting potato sprouts exist. Naturally derived clove oil can effectively suppress potato sprout growth, is currently used in the potato industry, and is approved for organic use. Research at the University of Idaho also suggests other essential oils, such as spearmint and peppermint, can be used for potato sprout control.[193]

The petitioner suggests that "taint" or off taste can result from the use of natural oils, yet research has found that even multiple applications of clove oil did not affect the taste of potatoes.

Methods such as temperature control and cultivar selection can also be used to influence the natural dormancy period and to delay sprouting. Research demonstrates that potatoes stored at 38 to 45 degrees F and at greater than 90 percent humidity will store for up to six months.

Packing a few apples with potatoes also helps to keep them firmer and prevent sprouting due to the small amounts of ethylene produced. Chloropropham is currently the primary conventional anti-spouting agent utilized in the U.S. potato industry, yet many in the industry are preparing for a time when the compound could be more strictly limited or even banned by the EPA due to concerns over the impact on human health[194].

In the search for alternative sprout inhibitors for the conventional market, Airgas, the largest U.S. distributor of industrial, medical and specialty gases, was granted registration

---

191 http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5109095
192 http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5110267
193 http://extension.uidaho.edu/kimberly/2013/04/potato-sprout-control/ and http://www.cals.uidaho.edu/edcomm/pdf/CIS/CIS1120.pdf
194 http://pmep.cce.cornell.edu/profiles/extoxnet/carbaryl-dicrotophos/chlorpropham-ext.html

in the fall of 2012 for the use of ethylene as a sprout inhibitor by the EPA. It is currently the only company in the country permitted to sell ethylene for this application. Airgas has partnered with Techmark, Inc., a Michigan-based company that represents BioFresh for sales of the technology in the U.S. Unlike other sprout inhibitors, ethylene does not leave residues and is used at concentrations of less than 10 ppm. Protective equipment is not required by law at levels less than 1000 ppm. Ethylene gas is currently on the National List to regulate pineapple flowering and for the postharvest ripening of tropical fruit and degreening of citrus. Its use for inhibiting potato sprouting should be considered before adding a lesser studied synthetic (3D2) to the NL.[195]

Health concerns

No peer-reviewed studies were found that address human health effects of 3-decene-2-one, as petitioned for potato sprout inhibitor thermal fog. The MSDS for the petitioner's product states that long-term toxicological effects of 3D2 as used for intended use have not been determined.

Exposure warnings for skin, eyes, and lungs are listed, and recommendations for the use of extensive personal protective equipment (PPE), including a respirator, are listed by the manufacturer. Additionally, the MSDS includes a precautionary statement that "care should be taken with chemicals that have not been thoroughly investigated."[196] Organic farming should incorporate best practices for risk reduction ("the precautionary principle") and prohibit pesticides that have unknown effects on human health. Although 3-decene-2-one has been approved as a food additive, and occurs naturally in some foods such as mushrooms and yogurt, the effect of an increased dose received from residue on potatoes in the human diet has not been studied.

In a recent review of the petitioner's application for use of 3-decene-2-one in the Netherlands, the European Food Safety Authority (EFSA) identified a critical area of concern, specifically that no reliable reference values could be derived for the presence of positive genotoxicity results and therefore they could not finalize a risk assessment for individuals, such as operators, workers, and residents.[197]

Environmental concerns

The proposed method of applying 3-decene-2-one is indoor thermal fogging, which the EPA considers a non-significant risk to the environment. Yet, in the aforementioned EFSA peer review of 3-decene-2-one, the applicant also did not provide enough information to address the effect of water treatment processes (e.g. washing of potatoes treated with 3-decene-2-one) and the resulting residues that might be present in surface water. Due to several identified data gaps, the information available was deemed insufficient to

---

[195] http://www.potatogrower.com/2013/08/using-ethylene

[196] http://www.amvac-chemical.com/products/documents/SmartBlock%20MSDS%20369-5.pdf

[197] EFSA Journal 2015;13(1):3932 http://www.efsa.europa.eu/en/efsajournal/doc/3932.pdf

determine potential harmful effects on human health, including that of vulnerable groups, or on animal health, through drinking water.

CONCLUSION

The Cornucopia Institute **opposes** the addition of 3-decene-2-one to the National List because it fails OFPA's criteria for inclusion on the National List: unknown impact on humans and the environment, incompatibility with organic practices, and because alternatives exist.

DISCUSSION DOCUMENT

Contaminated Inputs Plan

SUMMARY

The Crops Subcommittee's plan to address contaminated farm inputs is to consider off-site feedstocks/pathways and address the following questions:

- What contaminants might be present?
- What contaminants might survive currently prescribed requirements for composting?
- Is there a way to restrict the source so that contaminants would be removed (e.g., ask a farmer whether arsenic is fed to poultry or herbicides applied to hay)?
- If there are still remaining contaminants, do they exceed unavoidable residual contamination levels from a historical, but not current, use of a toxic material?
- Are there treatments that could be applied to the compost that eliminate those contaminants?

DISCUSSION

Inadequacies of the plan

The current NOSB plan for addressing contaminated farm inputs **will do nothing to prevent continued crop failures on organic farms due to persistent herbicides including compost carryover and drift from neighboring agricultural operations**.

The suggestion to "restrict the source so that contaminants would be removed" is nearly **impossible** when contaminants arrive through irrigation water, or drift, and sources of organic matter come from potentially multiple farms over multiple years. Putting organic farmers out of business is currently as simple as using contaminated water from irrigation ditches, a neighbor spraying herbicides that are effective in the parts per billion range on a windy day, or obtaining inaccurate information about source material.

It is unacceptable that farmers should have to apply treatments to compost to eliminate contaminants. In the case of pyridine carboxylic acid herbicides, this is not even possible due to its persistent longevity. In addition, “unavoidable residual contamination levels” could be established for persistent herbicides with respect to minimizing harm to humans, but levels below machine detection can’t result in a failed crop (parts per billion).

Unacceptable persistence

Below is information provided by Dow AgroSciences explaining precautions and restrictions on aminopyralid herbicides. Chemicals that inflict damage at such small amounts to cash crops and that are persistent for years should never have been approved by the EPA. These pyridine carboxylic acid herbicides are sold under the trade names Chaparral, CleanWave, ForeFront, GrazonNext, Milestone, Opensight, and Pasturall.

The following is from Dow AgroSciences’ Aminopyralid Use Precautions and Restrictions:

- Grasses grown for hay **must not be exported** outside the United States.
- Manure and urine from animals consuming grass or hay treated with this product may contain enough aminopyralid to cause injury to sensitive broadleaf plants.
- **Do not use hay or straw from areas treated** with aminopyralid or **manure from animals feeding on hay treated** with aminopyralid **in compost**.
- **Do not plant a broadleaf crop** (including soybeans, sunflower, tobacco, vegetables, field beans, peanuts and potatoes) in fields treated with manure from animals that have grazed forage or eaten hay harvested from aminopyralid-treated areas **until an adequately sensitive field bioassay is conducted** to determine that the aminopyralid concentration in the soil is at a level that is not injurious to the crop to be planted.
- **Do not plant a broadleaf crop in fields treated in the previous year with manure from animals that have grazed forage or eaten hay harvested from treated areas** until an adequately sensitive field bioassay is conducted to determine that the aminopyralid concentration in the soil is at a level that is not injurious to the crop to be planted.
- **Do not rotate to any crop from rangeland**, permanent pasture or CRP acres within one year following treatment. Cereals and corn can be planted one year after treatment. Most broadleaf crops are more sensitive, and can require **AT LEAST 2 years depending on the crop and environmental conditions**. **Do not plant a broadleaf crop until an adequately sensitive field bioassay shows that the level of aminopyralid or metsulfuron present in the soil will not adversely affect that broadleaf crop.**

Dow AgroSciences *Solutions for The Growing World*

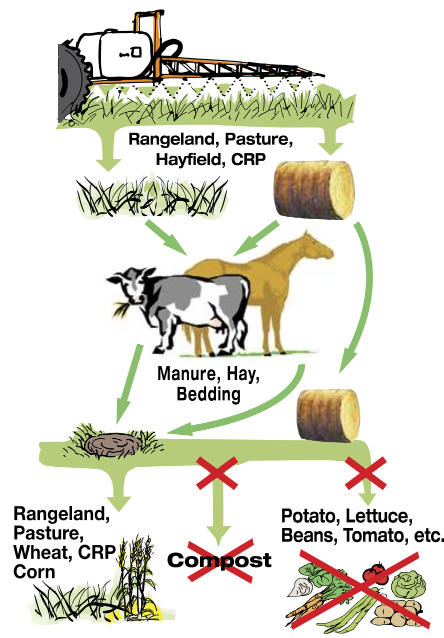
Aminopyralid Use Precautions and Restrictions

- Grasses grown for hay must not be exported outside the United States.
- Manure and urine from animals consuming grass or hay treated with this product may contain enough aminopyralid to cause injury to sensitive broadleaf plants.
- Do not use hay or straw from areas treated with aminopyralid or manure from animals feeding on hay treated with aminopyralid in compost.

Grazing and Haying Restrictions on Aminopyralid-treated Grass

- Do not transfer grazing animals from areas treated with the product to areas where sensitive broadleaf crops occur without first allowing 3 days of grazing on an untreated pasture. Otherwise, urine and manure may contain enough aminopyralid to cause injury to sensitive broadleaf plants.
- Do not use treated plant residues, including hay or straw from treated areas, or manure from animals that have grazed forage or eaten hay harvested from treated areas within the previous 3 days, in compost, or mulch or mushroom spawn that will be applied to areas where commercially grown mushrooms or susceptible broadleaf plants may be grown.
- Do not spread manure from animals that have grazed or consumed forage or eaten hay from treated areas within the previous 3 days on land used for growing susceptible broadleaf crops.
- Manure from animals that have grazed forage or eaten hay harvested from treated areas within the previous 3 days may only be used on pasture grasses, grass grown for seed, and wheat and corn.
- Do not plant a broadleaf crop (including soybeans, sunflower, tobacco, vegetables, field beans, peanuts and potatoes) in fields treated with manure from animals that have grazed forage or eaten hay harvested from aminopyralid-treated areas until an adequately sensitive field bioassay is conducted to determine that the aminopyralid concentration in the soil is at a level that is not injurious to the crop to be planted.
- Do not plant a broadleaf crop in fields treated in the previous year with manure from animals that have grazed forage or eaten hay harvested from treated areas until an adequately sensitive field bioassay is conducted to determine that the aminopyralid concentration in the soil is at a level that is not injurious to the crop to be planted.
- To promote herbicide decomposition, plant residues should be evenly incorporated in the surface soil or burned. Breakdown of aminopyralid in plant residues or manure is more rapid under warm, moist soil conditions and may be enhanced by supplemental irrigation.
- Do not rotate to any crop from rangeland, permanent pasture or CRP acres within one year following treatment. Cereals and corn can be planted one year after treatment. Most broadleaf crops are more sensitive, and can require at least 2 years depending on the crop and environmental conditions. Do not plant a broadleaf crop until an adequately sensitive field bioassay shows that the level of aminopyralid or metsulfuron present in the soil will not adversely affect that broadleaf crop.

Forage and Manure Management



The suggestion by Dow that it is up to the farmer to conduct bioassays on compost before spreading places an unrealistic burden on organic farmers that is nearly impossible to accurately measure given the following complications:

- It takes **at least** two months to see symptoms in bioassays, often longer and requires heated greenhouse space before the season begins.
- Farmers are not qualified to distinguish herbicide damage over other symptoms.
- Compost piles may not be uniform.
- Source materials continuously vary so that bioassays must be conducted endlessly.

Organic farmers should have the right to clean organic matter

The incorporation of organic matter into the soil from a wide range of sources has been used to maintain soil fertility for over 10,000 years and is central to organic farming. Incorporating organic matter and nutrients back into the soil prevents the need for synthetic fertilizers and mitigates pollution elsewhere. On- and off-farm inputs include compost, mined minerals, animal byproducts (fish, slaughterhouse waste), hay, mulches, and manures and organic farmers do society great benefit by recycling these hazardous waste products.

Among other contaminants, new herbicides introduced within the last ten years are preventing organic farmers from obtaining commonly available off-farm materials for compost including hay and manure from animals that eat treated hay and pasture.

Broadleaf-specific herbicides are sprayed on pasture and hay fields and pass unchanged through the digestive tract of farm animals ending up in their manure, where they do not break down for many years (even when properly and thoroughly composted).

As a result, manure/compost applied to organic fields containing trace amounts of these herbicides is affecting high value cash crops including tomatoes, potatoes, peppers, and beans, resulting in reduced yields to total loss. **This means that manure/compost, the most popular organic fertilizer and soil builder, is no longer trustworthy and therefore should no longer be used unless one is absolutely certain about all of the source hay fed to the animals.** This scenario results in environmental contamination by manure that cannot be returned to the soil.

Obviously, manure can contain other synthetic agrochemical residues that might not cause crop failures, but might contaminate crop tissues and pose risks to organic consumers and the environment on organic farms.

Other contaminants include heavy metals, neonicotinoid and bifenthrin and other insecticide residues, antibiotics, and GMO material. Herbicide contamination is perhaps "the canary in the goldmine" because of its direct impact on crop plants and farmer livelihood, but these other contaminants should not be ignored either.

Rather, persistent herbicide contamination of compost could be used as an example of how to educate organic farmers on the importance of obtaining organic inputs, when available.

For example, it has come to our attention from split organic-and-conventional industrial-scale egg operations that there is not an increased demand for organic chicken manure over conventional chicken manure (even though they have offered organic compost to certified organic farmers).

The NOSB should consider requiring that organic manure and compost be utilized when commercially available, much as is the case with organic seed.

The Cornucopia Institute would like to comment on a few additional issues that were not considered in the Discussion Document:

1. **The manufacturer of the herbicides should be held liable for losses incurred to farmers from unintentional contamination.** The NOSB should help establish a protocol for compensating farmers for production losses due to herbicide carryover

and should go on the record stating that these agricultural materials be removed from the market.

2. **Contamination of farm inputs is grossly underreported in the U.S. and globally.** Farmers are not always qualified to know why crops are failing or showing reduced yields. Even scientific professionals cannot oftentimes distinguish symptoms between pathogens, nutrient toxicities, and herbicide damage without expensive, comprehensive testing. Likewise, if farmers are able to determine that herbicide contamination has occurred, they are unlikely to come forward due to fear of losing the ability to market their produce. If a system is put in place to compensate for financial losses due to herbicide carryover, farmers are much more likely to investigate and report when contamination has occurred.

3. **The U.S. is not equipped to handle the problem of herbicide contamination of hay, manure, and composts.** From the Discussion Document: "No government or independent lab exists in the United States that can adequately test for aminopyralids in compost at or below the 1 ppb level."

   Many sensitive crop plants show symptoms well below the 1 ppb level. "Only the herbicide manufacturers (Dow Agrosciences and DuPont) are currently capable of testing for herbicides in complex matrices with high organic content such as composts and manures at the low part-per-billion levels at which sensitive garden plants are impacted."

   It is extremely problematic that we are leaving testing in the hands of the manufacturers producing the chemicals and depending on them to incriminate themselves with the results. In past cases of herbicide contamination, regulators have been unable to identify all sources of contamination because of the lack of testing.

4. **Tracking herbicide-contaminated organic matter is nearly impossible.** Often organic matter goes through many hands and information about chemicals used is lost. For examples, a hay farmer sprays aminopyralids to get rid of broadleaf weeds, sells the hay to a horse farmer, who then gives the manure to a composting facility that then sells compost to the farmer to grow vegetables. Information may be lost in each step.

5. The only solution provided to farmers thus far to avoid input contamination is to conduct a bioassay**. It is entirely unrealistic to put the responsibility of conducting bioassays on farmers.** This has been the recommendation of the chemical manufacturers and is faulty for many reasons.

   a. It is impossible to ensure that a sample used in the bioassay is representative of the whole.
   b. Sensitive plants often take several months to show symptoms after being planted in contaminated organic matter.

c. Farmers are not trained to distinguish symptoms of herbicide exposure from other symptoms such as nutrient deficiencies, toxicity or viruses.

6. The EPA must consider the fate of herbicides in compost when evaluating the registration of persistent herbicides.

CONCLUSION

With the increase in the use of persistent chemicals, including herbicides and insecticides, organic farmers are no longer able to trust that organic matter inputs and irrigation water are free of these prohibited materials. They will continue to be put out of business by these materials.

Persistent chemicals need to be banned from production because it is nearly impossible for organic farmers to be clean of these materials once they are produced. Farmers should not be held responsible for contamination and should be compensated by the manufacturer of the herbicides until they are banned.

2016 SUNSET MATERIALS

Ferric Phosphate– 2016 Sunset

SUMMARY

The Cornucopia Institute **opposes the relisting of ferric phosphate** because it fails all three of OFPA criteria: health and environmental impacts, essentiality, and compatibility with organic practices when used with EDTA as an effective slug and snail bait.

Ferric phosphate is listed at §205.601 as a slug and snail bait. However, research indicates that ferric phosphate is ineffective as a slug and snail bait without EDTA.[198] In addition, according to the Technical Report, **all of the ferric phosphate slug and snail baits currently marketed in the U.S. contain EDTA in their formulations.**[199]

The Cornucopia Institute recommends **the removal of ferric phosphate from the National List based on independent research that demonstrates its use as a slug and snail bait is only effective with the addition of a chelating agent such as EDTA.**

---

[198] Henderson, I., Triebskorn, R. 2002. Chemical control of terrestrial gastropods. In: *Molluscs as Crop Pests* (Ed. G.M. Barker). CABI Publishing, Wallingford, UK, pp. 1–31.
[199] http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5100083

Rationale:

- Ferric phosphate is not effective alone as a slug and snail bait as it is currently listed on the National List.[200]
- EDTA, present in all slug and snail baits in the U.S., is toxic to soil microorganisms and non-target species, including earthworms, and can contribute to groundwater contamination. It is persistent (does not degrade quickly) in the environment and raises concerns for human health and calcium absorption.[201] Its addition to the National List is unlikely.

DISCUSSION

Ferric (iron) phosphate is a simple iron salt. Metallic compounds, like iron phosphate, are known to quickly disperse when applied to the soil without a chelating agent such as EDTA.

In 2007, the NOSB Crops Subcommittee voted to reject the petition to include sodium ferric hydroxy EDTA on the National List as a slug or snail bait because of the potential for EDTA to be harmful to the environment.

In 2009, ferric phosphate was petitioned to be removed from §205.601 by Steptoe & Johnson Law Firm representing the manufacturers of a competing product under the argument that it is ineffective without EDTA. The Crops Subcommittee voted to keep ferric phosphate on the National List under the view that the generic active ingredient needs to be considered separately from any other ingredients.

The Crops Subcommittee brought up five items that need further discussion. The Cornucopia Institute's comments appear below each question:

5. **Is ferric phosphate alone an effective molluscicide?**

   There are no studies that definitively conclude that ferric phosphate alone is an effective molluscicide without the addition of a chelating agent.

6. **Can ferric phosphate be combined with other ingredients besides EDTA and still work?**

   EDTA and other related compounds (chelating agents) such as EDDS (a structural isomer of EDTA that is biodegradable and used outside the U.S.) are the only known

[200] Henderson, I., Triebskorn, R. 2002. Chemical control of terrestrial gastropods. In: *Molluscs as Crop Pests* (Ed. G.M. Barker). CABI Publishing, Wallingford, UK, pp. 1–31.
[201] EC (European Communities). 2004. European Union Risk Assessment Report for edetic acid (EDTA). European Chemicals Bureau Volume 49. http://www.baua.de/de/Chemikaliengesetz-Biozidverfahren/Dokumente/RAR_061.pdf?__blob=publicationFile&v=2

materials that allow ferric phosphate to work as an effective molluscicide. EDDS is less persistent but has unknown effects on soil microbial communities.[202]

7. **Are there reasons for concern about EDTA beyond a tolerance exemption, such as effects on soil organisms or contamination in groundwater?**

   EDTA has shown to cause a negative effect on soil microbial communities (decrease in dehydrogenase activity and basal respiration) as well as lowered yields in some crops.[203]

   EDTA and other chelating agents have the potential to pollute groundwater by leaching metals from soils.[204]

8. **Does the EDTA as used with ferric phosphate pose the same concerns as the EDTA reviewed as part of sodium ferric hydroxyl EDTA?**

   Clearly, yes. The concerns over the detrimental movement of metals in soils and river sediments, and the slow rate of biodegradation are still relevant. [205]

9. **Are there any unbiased studies that back up the findings of Edwards et al. as cited in the Technical Report or with contrasting results?**

   There is not enough evidence to conclude whether ferric phosphate molluscicides containing EDTA are toxic to earthworms at concentrations typical of application rates. The few studies that have been done test EDTA at higher concentrations or have conflicts of interest.[206, 207]

Crops Subcommittee discussions and vote

On 1/20/15, Crops Subcommittee members voted on the motion to remove ferric phosphate from §205.601(h) Yes: 2, No: 3, Abstain: 0, Absent: 2, Recuse: 0. One member

[202] Tandy, S., Ammann, A., Schulin, R., Nowack, B. 2006. Biodegradation and speciation of residual SS-ethylenediaminedisuccinic acid (EDDS) in soil solution left after soil washing. *Environmental Pollution*:191-199.
[203] Edwards, C.A., Arancon, N.Q., Vasko-Bennett, M., Little, B., Askar, A. 2009. The relative toxicity of metaldehyde and iron phosphate-based molluscicides to earthworms. *Crop Protection* 28: 289-294.
[204] Nowack, B., VanBriesen, J.M. 2005. Chelating Agents in the Environment. In: *Biogeochemistry of Chelating Agents* (Eds. B. Nowack and J.M. VanBriesen). American Chemical Society Meeting, NY, NY, pp. 1-18. http://s3.amazonaws.com/publicationslist.org/data/nowack/ref-82/Nowack_VanBriesen%20(2005).pdf.
[205] Epelde, L., Hernandez-Allicia, J., Becerril, J.M., Blanco, F., Garbisu, C. 2008. Effects of chelates on plants and soil microbial community: Comparison of EDTA and EDDS for lead phytoextraction. *Science of the Total Environment* 401: 21-28.
[206] Langan, A.M., Shaw, E.M. 2006. Responses of the earthworm *Lumbricus terrestris* (L.) to iron phosphate and metaldehyde slug pellet formulations. *Applied Soil Ecology* 34: 184-189.
[207] Luhrs, U. 2009. Field Study to Evaluate the Effects of NEU 1166M on Earthworms. Appendix R provided with Neudorff, 2010. Docket # AMS-NOP-10-0021

felt that the inert ingredient EDTA is active. However, other members felt that ferric phosphate is essential and that there is a lack of non-synthetic alternatives.

CONCLUSION

The Cornucopia Institute **opposes the relisting of ferric phosphate under §205.601** because it is not effective without chelating agents that have known negative impacts to human health and the environment.

In addition, we believe that the full Board should discuss and vote on whether or not to relist all materials. **Therefore, we recommend that the Crops Subcommittee moves to remove ferric phosphate from the National List so that the full Board can consider this material**.

Hydrogen Chloride – 2016 Sunset

SUMMARY

The Cornucopia Institute is providing the following comments for the Board members' consideration as to whether or not to relist hydrogen chloride (anhydrous hydrochloric acid in the form of a gas) for use in cottonseed delinting. The current listing for hydrogen chloride (HCl) is scheduled to sunset on 9/12/2016.

Though HCl fails two of OFPA's three criteria—health and environmental impacts and compatibility with organic practices—HCl **may be** essential until high quality mechanical delinters or starch or clay-based coated seed are commercially available.

Hydrogen chloride is listed as a synthetic at §205.601 (n) for the removal of lint from cottonseeds so that seed can be mechanically planted. Hydrogen chloride gas is highly corrosive and extremely hazardous. Less corrosive acids, in particular sulfurous acid, are also currently used for cottonseed delinting. Sulfuric acid is the most common acid used in the United States and internationally.[208] Although commonly used for conventional crops, sulfuric acid is not allowed for use in delinting cottonseed under USDA organic regulations.

Mechanical delinting is in the final stages of development.[209,210] USDA/ARS Ag Engineer Greg Holt in Lubbock, Texas, patented a rotating drum concept in 2012 and has now produced a larger prototype capable of delinting 150 pounds of cottonseed per hour.[211] An economic incentive may be all that is required to get this design to market if a demand in

[208] http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5108710
[209] http://www.ferrooiltek.com/product_fc200delinter.html
[210] http://www.cottonfarming.com/research-promotion/mechanical-delinting-of-cottonseed-has-promise/
[211] http://www.ferrooiltek.com/product_fc200delinter.html

the organic sector were created. In addition, the organic cotton industry has testified that they would like to move away from hydrogen chloride if possible.

Starch-based cottonseed coatings are currently used conventionally and have shown to prevent seed-borne diseases in cotton and improve the germination rate over acid delinting.[212] A patented process called EasiFloTM, developed by Cotton, Inc., is a gelatinized corn starch coating that permits machine handling of cottonseed, and may be a better alternative to HCl delinting.

Rationale:

- The original TAP review, dated 2003, and limited scope TR from 2012, **do not discuss thoroughly the feasibility and environmental impact of alternative acids, starch coating, or new developments in mechanical delinting**.
- Lactic, sulfurous, and acetic acid appear to be less toxic alternatives than hydrogen chloride, a more corrosive acid. **However, there is no discussion in the TR of how alternative acids compare in terms of efficacy in different regions of the country where cotton is grown.** Sulfuric acid is currently used in the South and is readily applicable to small lots of cottonseed.[213] Is it a potential alternative for Texas cottonseed delinting too? This information is missing from the TR.
- Mechanical delinting eliminates the need to use any acid. **There is no mention in the TR of what it would take to get mechanical delinting to the marketplace**.
- L.T. Kincer manufactures both a saw delinter and a dilute sulfurous acid delinter. The effectiveness of these delinting machines needs to be researched.
- Currently, **all commercially available organic cottonseed is delinted by All-Tex Seed, Inc.** in Leviland, Texas, which uses hydrogen chloride in their delinting process, which may qualify HCl as essential for organic production.

DISCUSSION

Hydrogen chloride is used to remove lint from cottonseeds so that seeds can be mechanically planted. The gas-acid or dry acid delinting method using anhydrous hydrogen chloride is commonly used in the arid region of Texas. Hydrogen chloride gas is sprayed on the cottonseeds and the seed's moisture content causes the change into hydrochloric acid, which weakens the lint on the seeds. Hydrochloric acid and the gas hydrogen chloride are very corrosive, strong acids and great caution must be employed in their handling and use.[214]

The TR (line 104) states that acid delinting "has been so effective, that there has not been a strong economic incentive to develop alternative methods. Rather, improvements for acid delinting have consisted of building environmentally friendly processing plants, improving

---

[212] http://cottonfarming.com/home/issues/2014-05/Pg-Feature-Cotton-Board-sm.pdf
[213] Biradarpatil, N.K. and Macha, S. (2008) Effect of dosages of sulphuric acid and duration of delinting on seed quality of Desi cotton, Karnataka Journal of Agricultural Sciences, 22:4, pp. 896-897.
[214] http://pubchem.ncbi.nlm.nih.gov/summary/summary.cgi?cid=313#x27

safety measures and developing acid resistant equipment. The hazards and environmental restrictions associated with acid delinting are still important issues."

Human health risks

Depending on the concentration, exposure to any tissue may result in varying degrees of damage, including cell death and the exclusion of oxygen from a confined air space. HCl is so highly corrosive, even at more dilute concentrations, that chronic occupational exposure causes chronic bronchitis, dermatitis, gastritis, and photosensitization in workers. Prolonged exposure to low concentrations may also cause dental discoloration and erosion. Workers are at constant risk of lesions, ulcers, pulmonary edema, vomiting, and diarrhea, and even death from exposure if proper precautions are not met.[215]

Alternatives exist

The Cornucopia Institute believes that the TR is deficient in its discussion of alternatives.

A patented process called EasiFloTM is a widely used gelatinized corn starch based coating and permits machine handling of cottonseed.[216] Studies conclude that there are not significant differences between coated and acid delinted cottonseeds for precision planting.[217] The germination rate of coated cottonseeds has shown to be improved over acid delinted cottonseed.[218,219] In addition, clay-based coatings enable mechanical planting, and provide fungal protection for the seeds improving yields.[220] The feasibility of various coated cottonseed as an effective alternative to the acid delinting process for organic seed production has not been explored.

The question of suitability of using alternative weaker acids (lactic, sulfurous, and acetic acid) was not addressed in the TR nor was the possibility of mechanical delinting. If these are not satisfactory techniques for cotton delinting in Texas, then more extensive documentation of the inadequacies of these alternate methods must be provided.

Finally, USDA/ARS researcher Greg Holt should be consulted to determine what is needed to bring mechanical delinting from the final research stages into commercial production. Our conversations with Dr. Holt indicate that a unit capable of replacing the acid delinting

---

215 http://www.epa.gov/ttn/atw/hlthef/hydrochl.html

216 http://www.wholecottonseed.com/cottonseed-101/easiflo-cottonseed

217 Olivier, D.O. (2005) Evaluation of polymer coated cottonseed as an alternative method of preparing cottonseed for planting, Master's thesis, Texas Tech University.

218 McMichael, B.L., Burke, J.J., Hopper, N. and Wedegaertner, T. (2004) The influence of various delinting and priming treatments on cotton seedling emergence, development and yield [abstract]. National Cotton Council Beltwide Cotton Conference, January 1-9, 2004, San Antonio, Texas.

219 Calamaan, F.G., Cruz, R.S. and Catedral, I.G. (1996) Screening and evaluation of materials for cottonseed coating, Cotton Research Journal (Phillipines), 9:1&2, pp. 35-45.

220 Zeybek, A., Dogan, T. and Ozkan, I. (2010) The effects of seed coating treatment on yield and yield components in some cotton (*Gossypium hirsitum L.)* varieties, African Journal of Biotechnology 9:34, pp. 5523-5529.

process could be available in 2016. He should be invited to speak at an NOSB meeting as an expert, or at least at the Crops Subcommittee meeting in which this substance was discussed.

Environmental concerns

The TAP review indicates that approximately 8 to 12 pounds of hydrogen chloride are required in the delinting process of one ton of cottonseed. The release of large amounts of chlorine, carbon dioxide, carbon monoxide, or hydrogen chloride is possible from the process. There are performance-based standards set by the EPA for emissions for each of these gases, which the agency defines as Hazardous Air Pollutants.[221] Clearly, organic practices are not compatible with the release of any of these EPA-defined Hazardous Air Pollutants.

However, the negative environmental impacts of growing organic cotton are much lower than those of conventional, and organic cotton growers need access to organic seed. Currently, it is our understanding that all organic seed available commercially is delinted by All-Tex Seed Co. in Leviland, Texas, and they use hydrogen chloride in their delinting process. Whether or not this sole provider of organic cottonseed could or would switch to an alternative practice should HCl be removed from the list has not been researched. In addition, whether or not any company would be willing to provide starch-coated seed should be determined.

Crops Subcommittee discussions and vote

On 1/20/15, Crops Subcommittee members voted on the sunset removal of HCl from §205.601 as follows: Yes: 0, No: 5, Abstain: 0, Absent: 2, Recuse: 0. With the incomplete information they had access to, based on the deficient TRs, members discussed essentiality and that mechanical delinting is not yet available in the marketplace.

CONCLUSION

The Cornucopia Institute strongly **recommends that a new Technical Review be completed before hydrogen chloride can be considered for relisting under §205.601**. The current TR does not adequately discuss current research into mechanical delinting, starch and clay-based coatings, and alternative acids.

The Cornucopia Institute, subsequent to a new, comprehensive TR, remains **neutral** on whether or not to relist hydrogen chloride based on the outstanding questions related to the commercial availability of mechanical delinting and other alternatives.

In addition, we believe that it is the legally mandated role of the full Board to discuss and vote on relisting of all materials. **Therefore, we recommend that the Crops Subcommittee continue to *game the system* by voting to remove hydrogen chloride**

[221] http://www.epa.gov/ttn/atw/hlthef/hydrochl.html

from the National List so that the full Board can consider this material after a new TR is completed.

2017 SUNSET MATERIALS

Newspaper or Other Recycled Paper – 2017 Sunset

SUMMARY

Newspaper and recycled paper without glossy or colored inks are listed as synthetic substances in organic crop production under §205.601(b), for mulches, and §205.601(c) for compost feedstocks. The National List states, "…provided that, use of such substances do not contribute to contamination of crops, soil, or water."

The Cornucopia Institute **recommends the relisting** of this 2017 sunset material **only if an updated review confirms that the use of these materials does not contaminate crops, soil, or water.**

Rationale:

- The Technical Report from 2006 is outdated. There have been many changes in newspaper ink since then and an updated review is necessary for proper evaluation.
- A limited scope report on inks and glossy paper has been requested by the Crops Subcommittee; this has not been posted yet and the status remains unknown.
- There has been an exponential increase in the use of colored graphics and photography in daily papers since the last Technical Review was prepared and it is not easy to separate colored from black inks.

DISCUSSION

Newspaper and other recycled paper serve to suppress weed growth, moderate soil temperature, retain soil moisture, and add carbon to compost. Before use, the paper must be examined to insure that glossy or colored ink is not included.

Newspaper and recycled paper listed at §205.601(b), (c) underwent a 2012 Sunset Review, with a unanimous decision to relist the substance under both uses, despite the fact that "the record lacks technical information on the listing and relisting of this use [as compost feedstocks]."[222] Technical information is still missing and the status of **a limited scope report that was requested by the Crops Subcommittee is unknown**.

There is a need for a full update to the 2006 Technical Report. Further investigation into the environmental impact of newspaper black ink and the wide variety of "other recycled

[222] http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5089516&acct=nosb

papers" is needed, as existing studies are limited and materials used to produce newspaper and recycled paper have changed since the 2006 TR. Recycled cardboard may contain new glues, inks, bleach, or protective (e.g., waxy) coatings. Plain brown corrugated cardboard is the least processed type of cardboard, and may have the least amount of chemical substances; use may need to be restricted to this type of cardboard.[223]

The 2006 TR does not include specific recycled cardboard material and the limited scope TR requested did not specify covering this area. According to the TR, chemical processes are used to remove the ink from recycled paper to be used as a feedstock. The material is then "pulped with water and often pulping chemicals such as sodium hydroxide (NaOH)" are used. After the pulp is processed, chlorine-free bleaches are used to remove impurities.[224] Are these the same procedures used today and what are the other chemicals involved? An updated TR is needed to address these issues.

Technical Report

The most recent TR found for newspaper and recycled paper was completed in 2006. For the **2012 Sunset Review**, the Crops Subcommittee requested a Technical Review for newspaper and other recycled paper that is still not available. **The committee issued a recommendation to relist, with the annotation that "when the requested technical report is received, the Crops Committee may reconsider its decision."**

For the 2017 Sunset Review, the Crops Subcommittee has again requested a limited scope TR on inks and their impacts. **The status of the requested TR from both 2012 and 2017 is unknown.** The 2006 TR and the original TAP from 1995 are outdated. Newspapers have changed dramatically over the years. For example, dioxin is currently less of a concern, and most inks are now soy-based, which removes some of the concerns relating to the petroleum-based inks of the past.

Pigments are still a potential concern and updated research is required to determine whether the listing should continue to prohibit the use of newspaper with colored inks. The prohibition against glossy paper is supported by the finding that they are more likely to have petroleum-based inks; however, a proposal that is supported by further research is needed. At a minimum, the limited TR requested is needed to answer questions on inks and their impact on the environment.

Alternatives exist

Non-synthetic mulch material includes wood chips, leaves, straw, bark mulch, grass clippings, compost, and cover cropping.

---

223 https://attra.ncat.org/calendar/question.php/can-i-use-cardboard-and-newspaper-as-mulch-on-my-organic-farm

224 http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5088918

Environmental concerns

While paper is biodegradable, studies have found that some inks in paper do not degrade fully.[225] The 2006 TR indicates that printing inks "contain pigments, oil carriers, additives, and resins. The specific 34 components of ink can vary widely." Pigments may be petroleum based and not 100% degradable. Printing ink may contain traces of heavy metals, which may transfer to the soil in small amounts. PAHs (polycyclic aromatic hydrocarbons) may be present in carbon-based printing ink, yet little is known about the impact of these substances on soil and plants.[226] The 2006 TR used information found in the 1995 TAP that indicated that PAHs break down and were not found in soil. Although the amounts of substances found in the soil may be minimal, **studies to support this information have not been cited.**

Human health concerns

The 2006 TR found no studies that assessed human health risks with the use of recycled newspaper or other recycled paper as mulch. The petroleum-based inks and PAHs present in recycled newspaper are potentially harmful to humans and the TR notes "that if the newspaper/paper were shredded, cellulose dust could present a risk to human health and should probably be considered more carefully than risks due to dermal exposure to inks (Original TAP Database, 1995)."

CONCLUSION

The Cornucopia Institute **recommends the relisting** of this 2017 sunset material **only if an updated review confirms that the use of these materials does not contaminate crops, soil, or water.**

Ammonium Soaps – 2017 Sunset

SUMMARY

The Cornucopia Institute **remains neutral on the relisting** of the 2017 sunset material ammonium soaps at §205.601(d) for use as a large animal repellent only, no contact with soil or edible portion of crop.

---

[225] http://hriresearch.org/docs/publications/JEH/JEH_1995/JEH_1995_13_2/JEH%2013-2-77-81.pdf
[226] https://etd.ohiolink.edu/!etd.send_file?accession=osu1354665028&disposition=inline

Rationale:

- Ammonium soaps are ineffective as a large animal repellant.
- They are harmful to aquatic systems.
- Fencing is the best alternative, although it may be cost-prohibitive.

DISCUSSION

Ammonium soaps are commonly called ammonium salts of higher fatty acids, also known as ammonium nonanoate. Ammonium nonanoate is produced by blowing air through oleic acid obtained from agriculturally produced edible fats and oils. This procedure produces a 50/50 mixture of nonanoic acid and azelaic acid which are separated by distillation. Noanoate is then mixed with ammonia dissolved in water. The final product is a soap, ammonium nonanoate. All of the mixture is converted to ammonium nonanoate with no byproducts and no need for purification.[227]

According to the petitioners, ammonium nonanoate is a naturally occurring soap formed from ammonium, a product of decomposition, and nonanoic acid which volatilizes from leaf surfaces and leaches into the soil. Azelaic acid, one of the byproducts of the first reaction, is also widely distributed in nature and is used in cosmetics, skin treatments (FDA approved), lubricants, hydraulic fluids, and polymers.[228]

Soap salts: Soap salts include the two pesticide active ingredients potassium salts of fatty acids (including potassium laurate, potassium myristate, potassium oleate, and potassium ricinoleate), and ammonium salts of fatty acids (ammonium oleate). Ammonium salts of fatty acids are used as a rabbit and deer repellent on forage and grain crops, on vegetables and field crops, in orchards, and on nursery stock, ornamentals, flowers, lawns, turf, vines, shrubs, and trees. The labels of all registered soap salts products with outdoor uses must bear the following label statement:

> *This product may be hazardous to aquatic invertebrates. Do not apply directly to water, areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water by cleaning of equipment or disposal of water.*

Labeling on ammonium salts products indicates that the use of protective eyewear (safety glasses, goggles, or face shield) is required. Labels must upgrade the ingredients statement by declaring potassium salts or **ammonium salts of fatty acids, rather than "soap."** Labels of products for crop uses must state specific crops and/or crop groups. [229]

---

[227] Smiley, R.A., and Best, C.E. 2009. Petition to Amend the National List. http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5083576
[228] Ibid.
[229] EPA. 1992. R.E.D. Facts. Soap Salts. http://www.epa.gov/pesticides/reregistration/REDs/factsheets/4083fact.pdf

Technical Report

The most recent TAP Report is from 1999.[230] The TAP Report contained very little information on ammonium soaps and stated that very limited information was available on the product, only that it was **used in a product called Repel** and that it was ineffective in preventing deer damage. **Repel has been taken off the market since this TAP Report was written**.

Past NOSB deliberations

Falcon Labs petitioned to include ammonium salts of fatty acids on the National List §201.601(b)(1) in 2006 as an herbicide, and again in 2009.[231]

The Crops Subcommittee has considered the use of ammonium salts of fatty acids as herbicides in organic crop production on three separate occasions (NOSB Committee Recommendation, 2007; NOSB Committee Recommendation, 2008, and NOSB Committee Recommendation, 2011). **Consistently, the committee has voted to reject this usage** (March 2007, November 2008, and December 2011). The basis for rejection each time was that there are many alternative weed management practices available and that the substance is **not compatible with the provisions of the Organic Foods Production Act** (OFPA) for general use on crops or cropland. The latest recommendation to reject ammonium soaps for use as and herbicide was in 2011 and was consistent with the former recommendations with a vote count of Yes: 6, No: 8.[232]

Environmental concerns

According to the EPA Reregistration Eligibility Document on Soap Salts, ammonium salts of fatty acids are used outdoors as a rabbit and deer repellent. The soap salts are degraded quickly in soil by microbes and do not persist in the environment. They are practically non-toxic to upland game birds and waterfowl. Their other potential hazards were estimated using data from the potassium salts.[233]

Acute and sub-acute toxicity studies using potassium salts of fatty acids indicate that soap salts are relatively non-toxic to birds, they are slightly toxic to both cold water and warm water fish species, and they are **highly toxic to aquatic invertebrates**. No studies regarding the effects of the soap salts on non-target insects were available for review and

---

[230] NOSB National List File Checklist. Crops: Ammonium Soaps. 1999.
http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5066967&acct=nosb

[231] Falcon Lab, LLC. 2006. Petition to Amend 201.601(b)(1) to Include Soap-Based Products on the National List of Substances Approved for Organic Production.
http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5057439

[232] Formal Recommendation by the National Organic Standards Board (NOSB) to the National Organic Program (NOP). Ammonium nonanoate petition.
http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5097084

[233] EPA. 1992. R.E.D. Facts. Soap Salts.

are therefore still required. In addition, product use rate information is needed to confirm that soap salts pose a minimal threat to endangered species.[234]

In 1988, the EPA determined that soap salts have "no independent pesticidal activity" in antimicrobial products, and must be classified as inert ingredients in those products. Antimicrobials that contain soap salts as active ingredients are considered misbranded.[235]

Human health concerns

Soap salts are of low toxicity when taken orally or briefly exposed to the skin and are placed in EPA Toxicity Category IV. However, they can cause mild to moderate irritation when exposed to the skin for longer periods of time. Ammonium salts can cause permanent eye damage if handled improperly.[236]

Fatty acids normally are metabolized, forming simple compounds that serve as energy sources and structural components used in all living cells. However, soap salts caused reproductive and mutagenic effects when administered to laboratory animals at high doses.[237] Thus, the EPA believes the risks of the soap salts to applicators and consumers are negligible. The risk of eye injury to applicators of the ammonium salts can be mitigated by use of protective eyewear.[238]

Essentiality

Some type of deer protection is essential to organic farming, but studies have shown that ammonium salts have limited usefulness as deer repellents.[239,240,241,242,243] Therefore, ammonium salts are not essential to organic production.

Alternatives exist

Fencing is the most effective method of protection. However, fencing may be expensive to install, depending on the type. The benefit of near-complete crop protection outweighs fencing installation costs.

---

234 Ibid.
235 Ibid.
236 Ibid.
237 Ibid.
238 Ibid.
239 USDA Forest Service. 2001. Comparison of Commercial Deer Repellents. (http://www.fs.fed.us/t-d/pubs/pdfpubs/pdf01242331/pdf01242331.pdf).
240 Hani, A. and Conover, M.R. USDA National Wildlife Research Center Symposia National Wildlife Research Center Repellents Conference. 1995. Comparative Analysis of Deer Repellents.
241 Conover, M. R. 1984. Effectiveness of repellents in reducing deer damage in nurseries. Wildl. Soc. Bull. 12:399-404.
242 1987. Comparison of two repellents for reducing deer damage to Japanese yews during winter. Wildl. Soc. Bull. 15:265-268.
243 DeYoe, D., and W. Schaap. 1987. Effectiveness of new formulations of deer repellents tested in Douglas-fir plantations in the Pacific Northwest. Tree Planters' Notes (Summer 1987):22-25.

Research studies have shown that ammonium salts are less effective at preventing deer damage than some other chemical repellents, though none have been observed to be greater than 50% effective.[244] The most effective chemical repellents are those with putrescent egg solids and predator odors as the main ingredient. However, their effectiveness is influenced by many factors including the availability of alternative food. In winter when there is less food available these repellents are not likely to be very effective in preventing deer damage.[245]

In a number of field tests, Big Game Repellent, containing putrescent egg solids, was found to be the most effective repellent, with an average of 50% reduction in browsing.[246, 247, 248,249] However, several authors reported that this reduction was still unacceptably high. No other repellent has consistently reduced deer damage by greater than 50% in field trials.

The chemical repellents that were studied were applied as a spray on the target plants (contact repellents). The National List specifies that ammonium soaps are not to have contact with crop plants. They are only to be used as area repellents.

Area repellents act mainly by odor. Examples of area repellents include human hair balls, Magic Circle (bone tar oil), soap bars, blood meal, feather meal, and meat meal. Area repellents are usually poured onto a cloth or bag and suspended above the ground at densities of up to 3,000/hectare.[250] The use of area repellents may be labor intensive. No instances of phytotoxicity or toxicity have been reported.

Contact repellents are sprayed or dusted on the foliage to protect plants from deer browsing. There are not many examples of contact repellents that are allowed in organic production; hot sauce is one that has been studied.

Fear is the mode of action for deer repellents containing ammonium soaps. Hinder, a commercial product containing 0.66% ammonium soaps of higher fatty acids, was tested and compared with other types of repellents. The product was applied as a contact

---

[244] USDA Forest Service. 2001. Comparison of Commercial Deer Repellents. (http://www.fs.fed.us/t-d/pubs/pdfpubs/pdf01242331/pdf01242331.pdf).

[245] Formal Recommendation by the National Organic Standards Board (NOSB) to the National Organic Program (NOP). Ammonium nonanoate petition. http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5097084

[246] Hani, A. and Conover, M.R. USDA National Wildlife Research Center Symposia National Wildlife Research Center Repellents Conference. 1995. Comparative Analysis of Deer Repellents.

[247] Conover, M. R. 1984. Effectiveness of repellents in reducing deer damage in nurseries. Wildl. Soc. Bull. 12:399-404.

[248] 1987. Comparison of two repellents for reducing deer damage to Japanese yews during winter. Wildl. Soc. Bull. 15:265-268.

[249] Conover, M.R. and G. S. Kania. 1988. Effectiveness of human hair, BGR, and a mixture of blood meal and peppercorns in reducing deer damage to young apple trees. East. Wildl. Damage Control Conf. 3:97-101.

[250] DeYoe, D., and W. Schaap. 1987. Effectiveness of new formulations of deer repellents tested in Douglas-fir plantations in the Pacific Northwest. Tree Planters' Notes (Summer 1987):22-25.

repellent. This type of application is not allowed by the NOP. Hinder was found to be less effective than repellents containing sulfurous odor, predator odor, or odors of rotten meat. In the research studies reported in the literature, the plants that were sprayed with the deer repellents were not crop plants, but trees. It would not be desirable to spray food plants with these objectionable odors even if they were allowed in organic production.[251]

None of the repellents eliminated deer browsing throughout the 18-week test. However, there were distinct differences among the repellents. In general, topical repellants performed better than area repellents. Fear-inducing repellents performed better than the other types of repellents. Eight of the nine repellants considered most effective for the first 11 weeks emitted sulfurous odors. Repellents containing decaying animal proteins, such as egg or slaughterhouse waste, were observed to be the most effective. [252]

Repellency is always susceptible to failure. Many factors other than aversive properties affect a repellent's efficacy. Ultimately, avoidance of the protected plant is affected by:

- Number and density of the animals inflicting problems;
- Mobility of the problem animals ;
- Prior experience of animals with foods and their familiarity with the surroundings;
- Accessibility of alternative sites;
- Availability of alternative foods;
- Palatability of the treated plants; and
- Weather conditions.[253]

Although some repellents, such as Big Game Repellent, consistently reduced browsing, none eliminated it entirely. Growers, therefore, should expect some browsing damage with any repellent. If the level of protection provided by repellents is unacceptable, growers might consider using other control methods such as deer fences and selective hunting of problem deer (based on applicable local law).[254]

Crops Subcommittee discussions and vote

November 17, 2005:
The Crops Subcommittee agreed with commenters who supported the renewal of ammonium soaps because their use does not negatively impact humans or the environment, is essential for organic production, and is compatible with organic production practices.

---

[251] Formal Recommendation by the National Organic Standards Board (NOSB) to the National Organic Program (NOP). Ammonium nonanoate petition.
http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5097084
[252] Ibid.
[253] Ibid.
[254] Ibid.

The Crops Subcommittee recommended the renewal of Soaps, ammonium for use as a large animal repellent only, no contact with soil or edible portion of crop. Committee vote: Yes: 5, No: 0; Board vote: Yes: 14, No: 0.

July 14, 2010:
The Crops Subcommittee recommended the renewal of Soaps, ammonium at §205.601(d) for use as a large animal repellent only, no contact with soil or edible portion of crop. Committee vote: Yes: 6; No: 0, Absent: 1, Abstain: 0.

CONCLUSION

Ammonium soaps have been shown to be **ineffective as a chemical repellent for preventing deer damage to plants**. It is approved as an area repellent, which requires a high density of treatment, up to 3,000 cloths or bags of soaked material per hectare. This can prove to be expensive and labor intensive and require ongoing maintenance for the grower. Considering the amount and frequency of application required and that the product is ineffective, the best option for a grower may very well be making the investment in installing a fence that will protect the crop. If the repellent is applied to an area near a body of water or the repellent leaches out of the cloths or bags and makes its way to a body of water, it would cause **damage to aquatic invertebrates** and subsequently impact the aquatic ecosystem.

For these reasons, The Cornucopia Institute **remains neutral on the relisting of the 2017 sunset material ammonium soaps** at §205.601(d) for use as a large animal repellent only, no contact with soil or edible portion of crop.

Lime Sulfur and Elemental Sulfur – 2017 Sunset

SUMMARY

The Cornucopia Institute **supports the relisting of the 2017 sunset materials lime sulfur and elemental sulfur** under §205.601 synthetic substances allowed for use in organic crop production (e) as insecticides, (i) as plant disease control with the added annotation stating: **use needs to document multiple alternative attempts to control target.** We recommend that the Crops Subcommittee investigate the particular uses of lime sulfur and elemental sulfur in plant disease and insect control to determine when they are necessary, and the committee should propose an annotation for specific uses.

Rationale:

- The broad-spectrum nature of both lime sulfur and elemental sulfur's toxicity means that non-target organisms will be affected depending on their sensitivity.
- Numerous preventative alternatives exist including crop rotation, highly diverse plantings, intercropping, companion planting, planting buffer strips and planting

cover crops, biological control organisms, applying compost, sanitation practices, natural and synthetic horticultural oils, aqueous potassium silicate, ammonium carbonate, and hydrogen peroxide.

- All targets of lime sulfur spray can be controlled to some extent utilizing biological methods, and the use of sulfur materials as insecticides and disease control agents can harm natural and released biological control agents contributing to the "pesticide treadmill" that organic practices are designed to avoid.
- Situations may exist where prevention methods are not effective. In these cases, lime sulfur and elemental sulfur may need to be used after less toxic or corrosive materials have been considered and/or trialed.

DISCUSSION

Lime sulfur is made through a chemical reaction between lime (calcium oxide) and sulfur. The lime is obtained by heating limestone to convert it to calcium oxide. The sulfur is obtained by the desulfurizing and processing of petroleum, natural gas and related fossil fuel resources to elemental sulfur.[255]

The U.S. EPA determined that lime sulfur rapidly degrades to calcium hydroxide and sulfur in the environment and human body. Residues of lime sulfur are exempt from the requirement of a tolerance.[256]

The commonly used fungicide application rate for lime sulfur is a two percent solution in water. This dilute lime sulfur solution has a pH of 10 and constantly releases small amounts of toxic hydrogen sulfide vapors.[257]

Lime sulfur is used as a fungicide and insecticide to control diseases such as powdery mildews, anthracnose, and scab, and insects such as spider mites on alfalfa, beans, clover, and fruits.[258] It is also commonly used to control the two spotted spider mite, broad mite and a variety of diseases such as plum pockets, black rot, spot of rose, San Jose scale, peach leaf curl, and several raspberry diseases.[259,260,261] Lime sulfur treatments can significantly

---

[255] Nehb W, Vydra K. 2006. Sulfur. In Ullmann's Encyclopedia of Industrial Checmistry (Wiley-VCH Verlag GmbH 640 & Co. KGaAed.), Wiley-VCH Verlag GmbH & Co. KGaA, Weinheim, Germany.
[256] Holb IJ, Schnabel G. 2008. A detached fruit study on the post-inoculation activity of lime sulfur against brown rot of peach (*Monilinia fructicola*). Australasian Plant Pathology 37: 454; doi:10.1071/AP08041.
[257] Venzon M, Oliveira RM, Perez AL, Rodríguez-Cruz FA, Martins Filho S. 2013. Lime sulfur toxicity to broad mite, to its host plants and to natural enemies: Toxicity of lime sulfur. Pest Management Science 69: 738–743; doi:10.1002/ps.3431.
[258] Tomlin C. 1994. Pesticide Manual 10th edition. British Crop Protection Council. Cambridge, U.K.: The Royal Society of Chemistry
[259] Janssen D. 2002. Lime-Sulfur: A fungicide used to control a variety of diseases. University of Nebraska-Lincoln Extension in Lancaster County. Retrieved October 16, 2014 from http://lancaster.unl.edu/hort/articles/2002/lime-sulfur.shtml.
[260] Bauernfeind RJ, Cloyd RA. 2012. Lime-Sulfur: A Multi-Use Pesticide. Kansas Insect Newsletter. Kansas State Research and Extension. Retrieved October 16, 2014 from http://entomology.k-state.edu/doc/extension-newsletters/ks-insect-newsletter-14-1.pdf.

reduce damage from apple scab.[262] It has the potential to control post-infection brown rot in organic stone fruit production.[263] With the expansion of organic farming, the amount of lime sulfur used in agriculture has increased in recent years.[264]

Elemental sulfur is also a synthetic material allowed for use in organic crop production as a fungicide and as an insecticide for use against ticks and mites. It is also allowed for use as a crop fertilizer and soil amendment, but that specific listing will not be discussed here. A 1995 TAP review and 2014 Technical Review were completed for lime sulfur. Elemental sulfur has a 1995 TAP review.

In general, lime sulfur prevents plant diseases by allowing sulfur to penetrate leaf tissues and kill germinated spores.[265] Elemental sulfur works in the same way; however, lime sulfur sticks to leaves without an adjuvant better than elemental sulfur. Once taken up by fungi, sulfur affects respiration, resulting in broad-spectrum toxicity.[266,267] Cellular exposure to sulfur results in the production of hydrogen sulfide, which is toxic to most cellular proteins.[268,269,270] The broad-spectrum nature of both lime sulfur and elemental sulfur's toxicity means that non-target organisms will be affected depending on their sensitivity.

---

[261] Venzon M, Oliveira RM, Perez AL, Rodríguez-Cruz FA, Martins Filho S. 2013. Lime sulfur toxicity to broad mite, to its host plants and to natural enemies: Toxicity of lime sulfur. Pest Management Science 69: 738–743; doi:10.1002/ps.3431.

[262] Holb IJ, Jong P de, Heijne B. 2003. Efficacy and phytotoxicity of lime sulphur in organic apple production. Annals of Applied Biology 142: 225–233.

[263] Holb IJ, Schnabel G. 2008. A detached fruit study on the post-inoculation activity of lime sulfur against brown rot of peach (*Monilinia fructicola*). Australasian Plant Pathology 37: 454; doi:10.1071/AP08041.

[264] Bauernfeind RJ, Cloyd RA. 2012. Lime-Sulfur: A Multi-Use Pesticide. Kansas Insect Newsletter. Kansas State Research and Extension. Retrieved October 16, 2014 from http://entomology.k-state.edu/doc/extension-newsletters/ks-insect-newsletter-14-1.pdf.

[265] http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5110631

[266] Holb IJ, Jong P de, Heijne B. 2003. Efficacy and phytotoxicity of lime sulphur in organic apple production. Annals of Applied Biology 142: 225–233.

[267] Beffa T. 1993. Inhibitory action of elemental sulphur on fungal spores. Canadian journal of microbiology 39: 731–735.

[268] Tomlin C. 1994. Pesticide Manual 10th edition. British Crop Protection Council. Cambridge, U.K.: The Royal Society of Chemistry

[269] Bauernfeind RJ, Cloyd RA. 2012. Lime-Sulfur: A Multi-Use Pesticide. Kansas Insect Newsletter. Kansas State Research and Extension. Retrieved October 16, 2014 from http://entomology.k-state.edu/doc/extension-newsletters/ks-insect-newsletter-14-1.pdf.

[270] http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5110631

As a soil amendment, elemental sulfur is used to lower soil pH. Since soil bacteria convert the sulfur to sulfuric acid, it is best to add sulfur to soil in the spring, when soil bacteria are active. Because this conversion to sulfuric acid is biological, not chemical, it takes place slowly, so pH change is gradual.[271] Elemental sulfur can be used in much the same way as lime sulfur for disease and insect control, but it is not as corrosive. Like lime sulfur, it is a broad-spectrum fungicide and insecticide for mites and ticks and therefore also affects some non-target organisms.

Alternatives exist

Crop rotation, highly diverse plantings, and planting cover crops help reduce fungal infections in annual crops.[272] Control of fungal infections in perennial crops may involve the use of certified, disease-free plants.[273] Cultural practices in perennial crops include removing diseased material and tilling in or mulching with chopped fallen leaves to promote decomposition and beneficial soil microorganisms.

In fruit trees and trellised crops such as grapes, regular pruning to open up the canopy enhances air movement and allows sunshine to penetrate, both of which hasten drying and minimize the moist conditions that support fungal infections.[274,275] Additional sanitation practices include the removal of pruned matter and diseased fruit thus limiting primary inoculum. Flaming leaf litter and weeds ruptures fungal cells.[276]

For insect and mite control, intercropping, companion planting, and planting buffer strips can attract beneficial insects and repel pests. Sanitation practices such as removing infested plant material are important to prevent future outbreaks.[277]

Additional alternative disease control measures include the use of biological control organisms. Biofungicides control plant diseases by various modes including direct attack of the pathogen, outcompeting the pathogen, triggering a defense mechanism in the host plant, or producing a chemical that is toxic to the pathogen. Biofungicides work best when applied preventatively.[278]

---

[271] http://blueberries.msu.edu/uploads/files/Lowering_Soil_pH_with_Sulfur.pdf.
[272] Holb IJ, Schnabel G. 2008. A detached fruit study on the post-inoculation activity of lime sulfur against brown rot of peach (*Monilinia fructicola*). Australasian Plant Pathology 37: 454; doi:10.1071/AP08041.
[273] Holb IJ. 2009. Fungal Disease Management in Environmentally Friendly Apple Production – A Review. In *Climate Change, Intercropping, Pest Control and Beneficial Microorganisms* (E. Lichtfouseed.), pp. 219–292, Springer Netherlands, Dordrecht
[274] http://blueberries.msu.edu/uploads/files/Lowering_Soil_pH_with_Sulfur.pdf
[275] Vaillancourt LJ, Hartman JR. 2005. Apple scab. American Phytopathological Society; doi: 10.1094/PHI-I-685 2000-1005-01. Retrieved October 27, 2014 from http://www.apsnet.org/edcenter/intropp/lessons/fungi/ascomycetes/Pages/AppleScab.aspx.
[276] http://blueberries.msu.edu/uploads/files/Lowering_Soil_pH_with_Sulfur.pdf
[277] Holb IJ, Schnabel G. 2008. A detached fruit study on the post-inoculation activity of lime sulfur against brown rot of peach (*Monilinia fructicola*). Australasian Plant Pathology 37: 454; doi:10.1071/AP08041.
[278] Swain S. 2014. Biological Fungicides: Do They Work and Are They Safe? University of California Cooperative Extension | Agricultural Experiment Station. Retrieved October 27, 2014 from http://ucanr.edu/blogs/blogcore/postdetail.cfm?postnum=13543.

Many other products are approved for use in organic crop production as fungicides and/or insecticides. Natural and synthetic horticultural oils, aqueous potassium silicate, ammonium carbonate, and hydrogen peroxide are examples. Some have use restrictions, such as ammonium carbonate, which can only be used in insect traps and is not allowed to contact crops or soils. Some are broad-spectrum fungicides and insecticides such as horticultural oils and insecticidal soaps.[279]

Essentiality

Although many sulfur products have great potential for use within organic production systems, their effectiveness, especially under moderate to high disease pressure, needs to be determined in field tests.[280] One study in New England compared the fungicidal activity of potassium bicarbonate, *Bacillus subtillis* (a biological control agent), and neem oil with a standard lime sulfur/sulfur protocol against apple scab. Both alternatives and sulfur products caused phytotoxicity, and some alternative products had more disadvantages in terms of non-target impacts.[281]

Situations may exist where prevention methods are not effective. In these cases, lime sulfur may need to be used after less toxic or corrosive materials have been considered and/or trialed.

Environmental concerns

Lime sulfur rapidly dissociates to form positively charged calcium particles and elemental sulfur. Even though the calcium particles are soluble in water, they are relatively immobile in soil because they bind to soil particles. Elemental sulfur has limited solubility in water so it is relatively immobile in soil. Therefore, the ability of lime sulfur to leach into nearby water bodies is considered negligible.[282]

The amounts of calcium and sulfur resulting from lime sulfur applications are not considered large enough to significantly change natural background levels of these elements in soil.[283] A small amount of hydrogen sulfide vapor may be released during normal use of lime sulfur, but the possibility of large-scale hydrogen sulfide formation is low. Both elemental sulfur and the polysulfides in lime sulfur are rapidly converted to water-soluble sulfur products that are actively used by plants and animals as essential sources of sulfur.[284]

[279] Holb IJ, Schnabel G. 2008. A detached fruit study on the post-inoculation activity of lime sulfur against brown rot of peach (*Monilinia fructicola*). Australasian Plant Pathology 37: 454; doi:10.1071/AP08041.
[280] http://www.oardc.ohio-state.edu/fruitpathology/organic/grape/organic.html.
[281] http://hortsci.ashspublications.org/content/46/9/1254.full.
[282] US EPA. 2005a. Environmental Fate and Ecological Risk Assessment for the Reregistration Eligibility Decision Document (RED) of Calcium Polysulfides, a Fungicide/Acaricide. US Environmental Protection Agency, October 2005. Retrieved October 16, 2014 from http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2007-0008-0004.
[283] Holb IJ, Schnabel G. 2008. A detached fruit study on the post-inoculation activity of lime sulfur against brown rot of peach (*Monilinia fructicola*). Australasian Plant Pathology 37: 454; doi:10.1071/AP08041.
[284] Ibid.

The environmental toxicity of lime sulfur varies depending on conditions and the species under consideration. Orally, lime sulfur is moderately toxic to mammals, and nontoxic to birds. However, the corrosiveness of lime sulfur causes irreversible eye damage and skin burns.[285] Contact toxicity studies show that lime sulfur is practically non-toxic to honey bees, but beneficial insects and mites demonstrate high levels of sensitivity, including decreased viability of larvae.[286,287]

Based on the mode of action of lime sulfur as a broad-spectrum fungicide, it is highly probable that it will have a detrimental effect on beneficial soil microorganisms.[288] This may especially be true for microorganisms that live on plant roots (such as nitrogen-fixing bacteria and mycorrhizae) since non-systemic fungicides sprayed on foliage have been found to accumulate at the root zone.[289] Because of its high alkalinity, large spills of lime sulfur could raise the soil pH and cause decreased viability and reproduction in sensitive populations of beneficial soil bacteria and fungi. Earthworm and nematode populations could also be affected.[290]

Phytotoxicity is commonly observed in plants treated with lime sulfur and elemental sulfur, but some plants are more sensitive than others. Application earlier in the morning and on cooler days helps prevent phytotoxicity because it increases with increasing temperature and humidity.[291,292] Symptoms include scorching of leaves, down- curled chlorotic brittle leaves, necrotic spotting, fruit russetting and/or fruit dropping/decreased yield.[293]

In sufficient quantities, calcium released in soils from lime sulfur could limit the absorption of less soluble nutrients leading to deficiencies.[294]

---

[285] Tessenderlo. 2013. Label: Lime-Sulfur Solution. Tessenderlo Kerley, Inc. Retrieved October 16, 2014 from http://iaspub.epa.gov/apex/pesticides/f?p=PPLS:102:::NO::P102_REG_NUM:61842-30.
[286] http://www.oardc.ohio-state.edu/fruitpathology/organic/grape/organic.html.
[287] Bauernfeind RJ, Cloyd RA. 2012. Lime-Sulfur: A Multi-Use Pesticide. Kansas Insect Newsletter. Kansas State Research and Extension. Retrieved October 16, 2014 from http://entomology.k-state.edu/doc/extension-newsletters/ks-insect-newsletter-14-1.pdf.
[288] Holb IJ, Schnabel G. 2008. A detached fruit study on the post-inoculation activity of lime sulfur against brown rot of peach (*Monilinia fructicola*). Australasian Plant Pathology 37: 454; doi:10.1071/AP08041.
[289] Plant Health Care. 2009. Effects of Fungicides on Mycorrhizal Fungi and Root Colonization. Plant Health Care, Inc. Retrieved October 24, 2014 from http://www.planthealthcare.com/pdf/Myconate/Fungicide%20effects%20on%20Mycorrhizal%20Fungi%20and%20Root%20Colonization%208-2009.pdf.
[290] Holb IJ, Schnabel G. 2008. A detached fruit study on the post-inoculation activity of lime sulfur against brown rot of peach (*Monilinia fructicola*). Australasian Plant Pathology 37: 454; doi:10.1071/AP08041.
[291] http://www.oardc.ohio-state.edu/fruitpathology/organic/grape/organic.html.
[292] Venzon M, Oliveira RM, Perez AL, Rodríguez-Cruz FA, Martins Filho S. 2013. Lime sulfur toxicity to broad mite, to its host plants and to natural enemies: Toxicity of lime sulfur. Pest Management Science 69: 738–743; doi:10.1002/ps.3431.
[293] http://www.oardc.ohio-state.edu/fruitpathology/organic/grape/organic.html.
[294] Jakobsen ST. 1993. Interaction between Plant Nutrients: IV. Interaction between Calcium and Phosphate. Acta Agriculturae Scandinavica, Section B – Soil & Plant Science 43(1): 6–10; doi:10.1080/09064719309410224.

It is likely that both target and non-target plants, insects, mites, and fungi will be harmed by lime sulfur or elemental sulfur treatments due to direct application and/or spray drift.[295]

Human health concerns

The corrosiveness of lime sulfur and some of its degradation products may cause irreversible eye damage and skin burns following contact.[296] Lime sulfur is moderately toxic by ingestion and highly irritating to the eyes, skin, and respiratory tract.[297] Poisoning incidents from exposure to lime sulfur have been reported with symptoms ranging from headache, dizziness, and eye irritation to nausea, vomiting, and diarrhea.[298]

Organic practices require that lime sulfur solutions be prepared in the absence of acids and synthetic phosphate fertilizers.[299] Combinations of lime sulfur with acidic substances (such as some fertilizers and insecticides) result in the production of toxic hydrogen sulfide gas that can be deadly at high concentrations. One such incident reported a farm worker's symptoms starting with difficulty breathing and progressing to respiratory failure, life-threatening metabolic acidosis, and coma.[300] However, agricultural workers on organic farms are unlikely to be exposed to hazardous levels of hydrogen sulfide when using lime sulfur as an insecticide or fungicide.

Elemental sulfur is not as caustic as lime sulfur. It is slightly irritating to the skin and slightly toxic if ingested. It has low inhalation toxicity but can cause irritation of the nose, throat, and lungs.[301]

CONCLUSION

Although The Cornucopia Institute **supports the relisting of the 2017 sunset materials lime sulfur and elemental sulfur** for use (e) as insecticides, (i) as plant disease control, we recommend adding an annotation that states: **use needs to document multiple alternative attempts to control target.** Due to the harm to non-target organisms, the Crops Subcommittee should investigate the particular uses of lime sulfur and elemental sulfur in plant disease and insect control to determine when they are necessary, and the committee should propose an annotation for specific uses (e.g., fire blight).

---

[295] Holb IJ, Schnabel G. 2008. A detached fruit study on the post-inoculation activity of lime sulfur against brown rot of peach (*Monilinia fructicola*). Australasian Plant Pathology 37: 454; doi:10.1071/AP08041.
[296] http://hortsci.ashspublications.org/content/46/9/1254.full.
[297] http://www.oardc.ohio-state.edu/fruitpathology/organic/grape/organic.html.
[298] CDPR. 2011. Pesticide Illness Surveillance Program. California Department of Pesticide Regulation. Retrieved November 18, 2014 from http://www.cdpr.ca.gov/docs/whs/pisp.htm.
[299] Holb IJ, Schnabel G. 2008. A detached fruit study on the post-inoculation activity of lime sulfur against brown rot of peach (*Monilinia fructicola*). Australasian Plant Pathology 37: 454; doi:10.1071/AP08041.
[300] OR-OSHA. 2014. Hazard Alert: Lime Sulfur reacts to form deadly Hydrogen Sulfide Gas. Oregon Occupational Safety and Health Administration. Retrieved October 27, 2014 from http://www.orosha.org/pdf/hazards/2993-19.pdf.
[301] http://www.cdms.net/LDat/mp3FF003.pdf.

Soaps, insecticidal – 2017 Sunset

SUMMARY

The Cornucopia Institute **supports the relisting of insecticidal soaps** on the National List under §205.601 synthetic substances allowed for use in organic crop production.

Rationale:

- Potential toxicity is minimal when used appropriately.
- Insecticidal soaps are not persistent as they are quickly metabolized in the environment.
- They are compatible with organic handling.

DISCUSSION

The use of soaps salts as pesticides has a long history. The first pesticide product containing soap as an active ingredient was registered in 1947. They were re-registered by the EPA in 1992.[302] The active ingredients in insecticidal soaps are the potassium salts of fatty acids (C_{12}-C_{18} saturated and C_{18} unsaturated). These salts are also on the EPA's List of Minimal Risk Inert Ingredients (EPA 4A list).

Insecticidal soaps are derived chemically by reacting potassium hydroxide (lye) with naturally occurring plant oils or animal fats and thus are considered synthetic products.[303] However, they are listed in OFPA as exempt synthetic compounds under 2118(c)(1)(B)(i) and in Subpart C of the NOP rule under §205.601 (e), synthetic substances allowed for use in organic crop production.

Two other soap products are included as well on the Sunset 2017 Materials list: herbicidal and algicide/demossers for which Technical Reports were requested and are due before the spring 2015 NOSB meeting. However, no TRs are being developed for insecticidal soaps[304], perhaps because the algicide/demossers soaps have the same active ingredients, even though their commercial concentrate and ready-to-use formulations can be quite different.

As an example, a leading commercial brand's algicide/demosser concentrated formulation contains ~29% ethyl alcohol and 1% isopropanol in addition to the 40% potassium salts of fatty acids, as opposed to the same brand's insecticidal soap concentrated formulation that contains 40% potassium salts of fatty acids and 60% water. Concentrated formulations are diluted before use; ready-to-use formulations typically contain ~2% soap.

---

302 EPA RED 1992
303 NOSB 1994 TAP Review
304 The Organic Quarterly, October 2014 NOP Newsletter

Accordingly this discussion will focus on insecticidal soaps which only contain potassium salts of fatty acids as the active ingredient. If another active ingredient is added, such as pyrethrins, it becomes a soap-based insecticidal product and must be registered separately with the EPA. This is clearly stated in the EPA RED 1992 document:

> *Registered products containing soap salts as well as other active ingredients will be reregistered once the other active ingredients also are determined to be eligible for reregistration*.

Insect pests targeted

Insecticidal soaps are used to control soft-bodied insect pests such as aphids, thrips, whiteflies, psyllids, sawfly larvae, spider mites, etc.

They are strictly a contact insecticide which causes death by disrupting the exoskeleton in insects.[305]

International regulations

Insecticidal soaps are approved for use under the European and the Canadian Standards for organic production.

Human health concerns

The Food and Drug Administration (FDA) classifies potassium salts of fatty acids as GRAS (generally recognized as safe) to humans.[306] Fatty acids are normally metabolized by the cells, where they are oxidized to simple compounds for use as energy sources and as structural components utilized in all living cells. Potassium is normally part of the body's metabolism and electrolyte balance.[307] As such, soaps are virtually non-toxic to humans, but they can cause mild to moderate skin irritation (although not dermal sensitizers) and are severe eye irritants, so applicators and handlers must wear protective gear as indicated on the labels of commercial products.[308]

Environmental concerns

Acute toxicity has been found to be low for mammalian and avian species and low for bees and hard-bodied insects. Toxicity to aquatic organisms has been found to be moderate for fish and high for aquatic crustaceans.[309] Another organization has concluded that

---

305 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.

306 http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=172.863

307 EFSA Journal 2013;11(1):3023

308 EPA RED 1992

309 http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=172.863

commercial uses of soap salts pose minimal risks to wildlife.[310] Bioaccumulation hazards are considered low in mammalians because fatty acid are readily metabolized and potassium is readily excreted by the kidney and exposure to potassium salts will not increase the body burden of potassium.

Potassium salts of fatty acids can be phytotoxic if used in direct intense sunlight or improperly applied.[311] As with all sprays, foliar exposure by drift to terrestrial plants can be of concern, although spray drift exposure from spot treatments are not expected to produce the same amount of exposure as with broadcast spraying.[312]

Because potassium salts of fatty acids are either integrated in the soil matrix or quickly (within a day) degraded due to soil microbial activity, there is no anticipated persistence hazard and chronic toxicity via long-term exposure is of low concern.[313]

Contamination of aquatic ecosystem can be of concern due to the moderate toxicity to fish and high toxicity to aquatic crustaceans.[314, 315] However, long-chain soap salts readily precipitate with metal ions (Mg, Fe, Ca, etc.), which are ubiquitous in aquatic environments, significantly limiting soap bioavailability. There exists an uncertainty regarding the fate of shorter chain-length fatty acid salts in aquatic environments due to a lack of existing data. However, the acute toxicity data obtained using a representative short-length fatty acid species indicate that it is not above acceptable risk levels.[316] Furthermore, no chronic effects are expected in aquatic environments as the half-life in surface waters of salts with various chain length fatty acids range from a half-day to 2.6 days.[317]

The manufacturing process (saponification of fat with a base) generates glycerol (glycerin), a byproduct widely utilized in various industrial processes, but in case of environmental release glycerin is readily metabolized by microorganisms. The other potential byproduct would be the unreacted potassium hydroxide; however, since 90% to 100% of the base is generally used in the reaction, the small amount of unreacted base becomes part of the soap formulation and is readily incorporated into the soil matrix.[318]

Essentiality; alternatives exist

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

---

310 HERA, 2003. Fatty Acid Salts (Soap) Environmental Risk Assessment Draft.
311 http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=172.863
312 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
313 HERA, 2003. Fatty Acid Salts (Soap) Environmental Risk Assessment Draft.
314 http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=172.863
315 HERA, 2003. Fatty Acid Salts (Soap) Environmental Risk Assessment Draft.
316 Ibid.
317 Ibid.
318 http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=172.863

prevent or control the target pest. These provisions suggest various management practices and approaches to prevent or control crop pests:

- Crop rotations, crop nutrient, and soil management practices (healthy soil implies healthy plants that are naturally more resistant to pests); sanitation measures to remove habitat for pest organisms; cultural practices that enhance crop health, such as selection of plant species and varieties adapted to local conditions and resistance to prevalent pests.
- Mechanical or physical methods can also be utilized to control pest problems.
- Natural predator conservation and augmentation by way of development of habitat for natural predators (i.e., maintaining a wildflower buffer strip around fields) or introduction of predators or parasites of the pest species; non-synthetic controls such as lures, traps, and repellents can be effective control as well, either alone or in addition to the above-discussed approaches.

And finally, as a last resort, allowed synthetic substances can be used. There are several insecticides that can alternatively be employed:

- Horticultural oils;
- Sucrose octanoate ester;
- Elemental sulfur;
- Neem extract; p
- Pyrethrins;
- Diatomaceous earth;
- Kaolin clay BT;
- Boric acid; and others.

However, they all have different characteristics and toxicological profiles and do not necessarily effectively replace insecticidal soaps.

Finally, it is inevitable that beneficial insects and other non-target species will be impacted by the utilization of any allowed synthetic insecticides. Specific to insecticidal soaps, soft-bodied insects such as predatory mites will be negatively affected by their use. This potentially deleterious effect on beneficial insect populations can be minimized by judicious uses, such as spot applications on infested plants or field sections.

Alternatively, the Oregon State University's IPM program[319] suggests a strategic approach, the use of a knock-down spray with a compatible miticide prior to predator release if spider mites populations are high to help the establishment of the predatory mites. This is corroborated on the Planet Natural website[320] 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."

[319] http://oregonstate.edu/dept/nurspest/two-spottedmite.htm
[320] http://www.planetnatural.com/beneficial-insects-101/phytoseiulus-persimilis/

Technical Report

The only Technical Report available for these compounds ("soaps") is a 1994 TAP review[321] that closely follows the data from the EPA 1992 RED report[322] and exactly states the same conclusion. Most of the individual TAP reviews that are part of the 1994 TAP report are bare bones and do not present any new information.

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."

In the same section under 2119(m)7: "compatible", compatible is stated without any further explanation.

CONCLUSION

The final word from the EPA 1992 RED report: "In summary, based on the data reviewed, EPA finds that the soap salts will not cause unreasonable adverse effects on the environment."

Even though more extensive toxicological data was obtained on insecticidal soaps since the EPA RED 1992 report and the NOSB 1994 TAP review, it appears that insecticidal soaps are relatively safe to humans and the environment when used appropriately. Even if accidental environmental contamination were to occur, catastrophic damage and long-term effects would not be anticipated.

Vitamin D_3 – 2017 Sunset

SUMMARY

The Cornucopia Institute **does not support the relisting** of the 2017 sunset material Vitamin D_3 as a rodenticide under §205.601(g), synthetic substances allowed for use in organic crop production. 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 bioaccumulate.

[321] EPA RED 1992

[322] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=172.863

- Effective alternatives in line with OFPA include trapping and conservation of predator habitat.

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 of bones and moves calcium from the intestine to the blood.[323] Cholecalciferol is the form of Vitamin D_3 that is used as the active ingredient in rodenticides for gophers, mice, and rats. When ingested by rodents, it results in elevated levels of calcium in the blood leading to mineralization of major organs.[324, 325] Tissue damage results in heart problems, kidney failure, and eventually death.[326]

Vitamin D_3 was approved for use as a rodenticide in 1984 by the U.S. EPA.[327] In 2008, a risk mitigation decision by the EPA required Vitamin D_3 to be sold to general and residential 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.[328]

One of the key concerns about rodenticides in general is the effect on non-target species. Non-target species can be poisoned by either eating the bait directly (primary risk) or by predators or scavengers ingesting an animal that has already eaten bait (secondary risk).[329]

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. There was insufficient data available to assess secondary risk. However, data showed that Vitamin D_3 has a long retention time in the blood (25 days) and this could lead to a higher risk to predators or

---

323 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.

324 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

325 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

326 2011 Technical Report http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5089352&acct=nopgeninfo

327 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

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

329 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

scavengers compared to poisons that are eliminated quickly. It is unknown how long the retention time is in the liver of poisoned animals.[330]

Another concern of all rodenticides is their sublethal effect on birds and mammals. These effects are unknown and reproduction studies are needed to establish a no-observable-adverse-effects level (toxicity threshold).[331]

A New Zealand study noted that there are species differences in vulnerability to Vitamin D_3 and that variation among individuals even within a species occurs. Different bird species have considerable differences in their sensitivity to Vitamin D_3 and this means that 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 exhibited adverse reactions 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 should be discouraged by pet owners, especially dog owners.[332]

Essentiality

Rodent control is considered essential to crop production because major crop losses can occur to many high value crops. Rodents can also waste irrigation water by chewing holes in irrigation lines and causing leaks. Also, crop loss occurs when flood irrigation water goes down rodent burrows instead of down irrigation furrows. While many rodenticides exist, they are not approved for use on organic farms and they 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 don't involve chemicals. These include encouraging predators (putting up owl nest boxes for example or encouraging wetlands to attract raptor nesting), trapping, making areas less hospitable to rodents (remove shelter or food sources), and physical barriers (fences, trenches, irrigation).[333] Castor bean oil spray or pellets can also be used in organic production, although castor oil can also poison pets.[334] Sonic alarms and urea are also alternatives, but their effectiveness has not been studied.

---

330 Ibid.
331 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
332 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
333 https://attra.ncat.org/calendar/question.php/how_can_i_control_rodents_organically
334 2011 Technical Report http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5089352&acct=nopgeninfo

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.[335] 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.[336] Data from the Annual Poison Center Report show 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.[337]

The most vulnerable population for poisoning is children whose behavioral characteristics and small size make them particularly susceptible to toxins in the environment. EPA's 2008 requirement to sell Vitamin D_3 to the general public with only bait stations is meant to minimize Vitamin D_3 poisoning of children.[338]

Eating game from poisoned animals may also pose a threat. Human health hazards would be increased if the hunted animal was a primary consumer of the bait.[339] A New Zealand study demonstrated adverse reactions in dogs who ate poisoned possum meat and recommended that hunters should not take game from areas that have had Vitamin D_3 bait in the last one to three months.[340]

CONCLUSION

The Cornucopia Institute **rejects** the relisting of Vitamin D_3 on the National List under §205.601(g) Synthetic substances allowed for use in organic crop production. Vitamin D_3 is toxic to non-target organisms. Trapping is a safer, effective alternative that meets OFPA criteria.

---

[335] 2011 Technical Report http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5089352&acct=nopgeninfo

[336] Ibid.

[337] 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

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

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

[340] 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

Copper Sulfate & Fixed Copper Products – 2017 Sunset

SUMMARY

The Cornucopia Institute supports the relisting, as a "restricted use" material, of synthetic copper sulfate and fixed copper products, scheduled to sunset in 2017, provided that they are used in a manner that minimizes copper accumulation in the soil **with the added annotation stating: use needs to document multiple alternative attempts to control target.** We 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 propose an annotation for specific uses and rates.** Furthermore, we recommend setting a five-year average maximum application rate for copper products.

Rationale:

- **The use of copper sulfate as a fungicide should not be considered before adequate soil and cultural management practices are employed.**
- Numerous disease preventative **alternatives exist** including crop rotation, highly diverse plantings, intercropping, companion planting, planting buffer strips and planting cover crops, biological control organisms, applying compost, sanitation practices, natural and synthetic horticultural oils, aqueous potassium silicate, ammonium carbonate, sulfur, and hydrogen peroxide.
- 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 but some plant diseases do not respond to them.
- Situations may exist where prevention methods are not effective. In these cases, **copper may need to be used after less toxic materials have been considered** and/or trialed.
- There are soil types that are copper deficient and require copper supplementation.

DISCUSSION

Copper sulfate is a **synthetic substance** allowed for use (with restrictions) in organic crop production as described below:

- For plant disease control provided that it is 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.[341]

When copper sulfate and fixed copper products are used in agriculture, they eventually dissociate to form a positively charged copper particle that persists and accumulates in the environment.[342]

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.[343]

Coppers, fixed, allowed for plant disease control for organic crop production are also "copper products that are exempt from tolerance by the EPA."[344] 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, cuprous oxide. These materials "must be used in a manner that minimizes accumulation in the soil and shall not be used as herbicides."[345]

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. Labels were required to 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.

---

341 http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=79c4ebcacc3e33f160e0024456ef889f&n=pt40.24.180&r=PART&ty=HTML#se40.24.180_11021.
342 http://www.epa.gov/oppsrrd1/reregistration/REDs/copper_red_amend.pdf
343 http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=79c4ebcacc3e33f160e0024456ef889f&n=pt40.24.180&r=PART&ty=HTML#se40.24.180_11021.
344 http://www.epa.gov/oppsrrd1/reregistration/REDs/copper_red_amend.pdf
345 Ibid.

Technical Report

The 2011 TR is incomplete and out of date. There is no evidence of the method used to determine what is considered to be the maximum allowable level of concentration of copper that "minimizes residue." There is no discussion about the current concerns regarding grower dependence on the use of copper as a fungicide. **Many large-scale, split organic/conventional monoculture-style operations use frequent copper sprays as their primary disease management strategy**.[346] Fields may be abandoned after three years to prevent toxicity. The overreliance on copper for disease management is not in line

---

346 First hand observation by a Cornucopia Institute staff member while doing graduate research on hundreds of organic farms in the mid-Atlandtic.

with OFPA. Further investigation into the particular uses of copper products is needed to determine when they are necessary so that annotations for specific uses and rates can be proposed.

Essentiality to organic crop production

There are some diseases, such as black rot in grapes and late and early blight in tomatoes, for which no other fungicide, listed for organic use, is more than weakly effective.[347] If spraying a copper product is deemed necessary, severity of infection, forecasted weather, and growing conditions need to be taken into consideration to determine a spray schedule. Use of a spray schedule that alternates application of a copper material with a non-copper material should be considered to reduce the total amount of copper used.

In addition, there are some soil types that are copper deficient and require copper supplementation. In these cases, deficiencies should be documented and use should not exceed recommended supplementation rates.

Alternatives exist

Alternative methods for disease control for organic crops include growing with high plant diversity, selecting resistant plants and cultivars, managing nutrients and rotating crops. Adequate scouting for disease and hygienic practices such as carrying out diseased material, training and pruning perennial trellised crops to maximize air flow, and spacing plantings for maximal air flow also prevent disease.

Other approved organic pesticides can be used for pest and disease control including sulfur products, horticultural oils, neem oil, and bicarbonates[348] as well as hydrogen peroxide and salts.[349],[350]

---

347 https://www.extension.purdue.edu/extmedia/bp/bp-69-w.pdf.
348 http://www.oardc.ohio-state.edu/fruitpathology/organic/grape/organic.html.
349 Ibid.
350 https://www.extension.purdue.edu/extmedia/bp/bp-69-w.pdf.

Environmental concerns

Copper-based fungicides accumulate copper in the soil. Some of this copper is not available to living things because it forms biologically unusable complexes, however biologically available copper can cause toxic effects both in soil and in water.[351]

The toxic action of copper is attributed to its ability to deactivate proteins.[352] The long-term application of copper-based fungicides in vineyards was found to adversely affect soil microbial enzyme activity.[353]

Typical application rates of copper-based fungicides exceed toxicity levels for most animals studied.[354] Decreases in soil biodiversity, earthworm growth, and organic decomposition are observed as copper levels increase.[355] The effect of added copper on soil microorganisms depends on the species, soil pH, and organic content of the soil.[356,357]

Aquatic plants are more sensitive to copper than terrestrial plants. Copper can enter bodies of water by soil leaching, spray drift, or from direct water application.[358] When copper sulfate is released into waterways, there is an increased risk of fish mortality from "copper water toxicity, accumulation in sediment, and possible benthic community degradation."[359]

Copper sulfate applied at rates needed to control algae in rice production may kill frog species that feed on algae. Copper sulfate, and related copper substances, can also kill beneficial zooplankton resulting in negative affects to the benthic organisms that maintain the aquatic ecosystem.[360,361]

Human health concerns

---

[351] http://www.epa.gov/oppsrrd1/reregistration/REDs/copper_red_amend.pdf
[352] http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5089146&acct=nopgeninfo.
[353] http://www.sciencedirect.com/science/article/pii/S0038071710002956.
[354] http://www.epa.gov/oppsrrd1/reregistration/REDs/copper_red_amend.pdf
[307] Bogomolov DM, Chen SK, Parmelee RW, Subler S and Edwards CA. 1996. An ecosystem approach to soil toxicity testing: a study of copper contamination in laboratory soil microcosms. *Appl. Soil Ecol*., 4, 95-105.
[356] Lejon DPH, Martins JMF, Leveque J, Spadini L, Pascault N, Landry D, Milloux M, Nowak V, Chaussod R and Ranjard L. 2008. Copper dynamics and impact on microbial communities in soils of variable organic stutus. *Environ. Sci. Technol*., 42, 2819-2825.
[357] Hashem AR. 1997. Effect of heavy metal ions on the mycelia growth of some fungi isolated from the soil of Al-Jubail Industrial City, Saudi Arabia. *J. King Saud. Univ*., 9, 119-124.
[358] http://www.epa.gov/oppsrrd1/reregistration/REDs/copper_red_amend.pdf
[359] http://www.littline.com/images/Aquatic_Herbicide_Impacts.pdf.
[360]http://www.beyondpesticides.org/organicfood/action/fall2011/BP%20comments%20on%20coppersulfate.final.pdf.
[361] http://www.ibnature.com/copper-compounds-as-algaecides;
http://www.researchgate.net/publication/269398599_Effects of copper sulfate on zooplankton communities in ponds submitted to agricultural intensification

Symptoms from copper exposure include nausea, vomiting, headaches, and skin and eye irritation. Copper dust or powder causes the most irritation. Most copper compounds have low systemic toxicity due to their low solubility and absorption.[362]

The risk of acute exposure to copper is primarily to pesticide applicators. Concentrated copper products can cause irreversible eye damage. Prolonged or frequent skin contact can cause allergic reactions.[363]

NOSB Crops Subcommittee action

For the 2012 sunset of copper, the Crops Subcommittee was concerned about the impacts of copper sulfate on aquatic plants and animals. Concentrations of copper that would be found in a rice field are high enough to be toxic to amphibians. The committee relied on testimony of rice growers that the soil testing, as required by the annotation, did not result in increased accumulation of copper. Members of the subcommittee commented that research is needed into the uses of alternatives to copper sulfate. This includes terrestrial crop uses, which are not clearly defined, as well as use in rice.

Note: A new TR detailing this research has not been requested.

The 4/29/11 vote to relist copper products was Yes: 14, No: 0.[364]

CONCLUSION

The Cornucopia Institute **supports the relisting** of copper sulfate and fixed copper products on the National List. Some diseases have no effective alternative. However, in order to be able to ensure that the use of copper materials in organic production is **limited to that which is necessary and does not harm the environment**, the NOSB must solicit input on the current uses of copper products in organic production and annotate the listings to minimize use. There should be required regular soil testing and maximum loading rates.

Lignin Sulfonate – 2017 Sunset

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, we **support the relisting of lignin sulfonate**

---

362 http://www.epa.gov/oppsrrd1/reregistration/REDs/copper_red_amend.pdf
363 http://pmep.cce.cornell.edu/profiles/extoxnet/carbaryl-dicrotophos/copper-sulfate-ext.html.
364 http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5091705.

(2017 Sunset) for use as a dust suppressant, and as a chelating agent (7 CFR §205.601(j)(4)), but we **do not support** the listed use 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.

Rationale:

- Use of lignin sulfonate as a dust suppressant is an environmentally responsible practice to prevent erosion on roadways, but should be used only in combination with alternative dust controls such as vegetative cover.
- 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 silicate, sodium carbonate, or potassium carbonate).
- Lignin sulfonate is a safe chelating agent because the presence of polar and non-polar areas on the surface of the lignin molecules that physically bind to dust, but do not result in chemical changes.
- Lignin sulfonate should be removed for use as a plant or soil amendment because there are safer alternatives to increasing organic matter in soil that do not result in the same risks for high biological oxygen demand (BOD) in waterways.

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.[365]

Lignin sulfonates are negatively charged resulting in interactions with cations to form lignin sulfonate salts, such as sodium lignosulfonate, magnesium lignosulfonate,

---

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

ammonium lignosulfonate, and calcium lignosulfonate.[366] 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 change 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.[367] Soil binders are a temporary soil stabilization technique and therefore should only be used in conjunction with more permanent erosion control measures. Wood chips, gravel, and increased vegetation are more permanent solutions to roadway dust.[368]

The use of lignin sulfonate as a plant or soil amendment 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 agent (i.e., sodium silicate, sodium carbonate, or potassium carbonate).

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, potentially impacting aquatic organisms. Likewise, when lignin sulfonates are

---

[366] 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.

[367] 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

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

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.[369]

Alternatives exist

An alternative to lignin sulfonate for use as a floating agent in post-harvest handling of fruit is sodium silicate, an allowed synthetic substance for organic production.[370] Potassium carbonate and sodium carbonate were also found to be effective floating agents by researchers at Oregon State University.[371]

Though the use of lignin sulfonate as a dust suppressant is considered safe, alternative dust suppressants allowed for use in organic production include non-synthetic (natural) sources of magnesium chloride and calcium chloride.[372] 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 suppressant.[373] 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.[374]

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.

---

[369] 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

[370] Sugar, D and Spotts, A. 1986. Effects of flotation salt solutions on spore germination of four decay fungi and on side rot of pear. Plant Disease 70:1110-1112. http://www.apsnet.org/publications/PlantDisease/BackIssues/Documents/1986Articles/PlantDisease70n12_1110.PDF

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

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

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

[374] 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

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.[375]

International regulations

The Canadian General Standards Board allows the use of lignin sulfonate as a dust suppressant, formulant ingredient, and chelating agent.[376] 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.[377] As of 2009, calcium lignosulfonate is allowed by the CODEX Alimentarius Commission as a food additive.[378]

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 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).[379] Lignin sulfonate is not specifically discussed by the European Union Regulations.

Crops Subcommittee discussions

---

[375] 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.

[376] 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.

[377] 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.

[378] 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.

[379] 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.

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. During the 2017 Sunset Review the Crops Subcommittee will solicit comments about the petition to remove and whether or not it is essential as a flotation aid.

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 **support the relisting of lignin sulfonate** (2017 Sunset) for use as a dust suppressant and as a chelating agent (7 CFR §205.601(j)(4)) because of its safety and essentiality for these uses. However, we **do not support** the relisting of lignin sulfonate for use as 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.

<u>Ethylene Gas – 2017 Sunset</u>

SUMMARY

The Cornucopia Institute **opposes** the relisting of the 2017 sunset material 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 has unanswered questions, specifically how ethylene gas is applied and how it can be applicable to smaller growers.
- 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 ripening fruit. When ethylene gas is sprayed on pineapple plants chemical changes take place that stimulate the release of ethylene, leading to flowering and fruiting. Other substances commonly used for pineapple growth regulation but not listed for organic production are acetylene, calcium carbide and ethephon.[380]

According to the 2011 TR, application of ethylene gas is mixed into pressurized water and applied via boom sprayers in large pineapple farm operations. Application takes place 7-15 months after the planting. Smaller farm 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 that 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.**"[381]

Past NOSB deliberations

In March 2011, the Crops Committee 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 achieve higher yields through year-round production, and the benefit to large-scale operations, as opposed to smaller organic farms.[382] In April 2011 the Crops Committee met again "to consider new public comment 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.

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 are (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, and (3) alternative ethylene gas application methods that will make the material more feasible for small-scale production. **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.

Alternatives exist

---

[380] http://www.scielo.br/scielo.php?pid=S0006-87052005000400001&script=sci_arttext
[381] http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5067073
[382] http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5089523

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 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 produced increased amounts of ethylene and induced flowering when nighttime temperatures reached 25 degrees or less.[383]

According to the 2011 TR, 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 increases in the 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.[384] This cultural flower induction 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 effect of ethylene gas used for pineapple production is unlikely to harm the crops or the environment.[385]

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 and coordination problems may result from low-level exposure.[386]

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.

---

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

Microcrystalline Cheesewax – 2017 Sunset

SUMMARY

The Cornucopia Institute **remains neutral** on the relisting of the 2017 sunset material microcrystalline cheesewax on §205.601 Synthetic substances allowed for use in organic crop production.

Rationale:

- Though microcrystalline cheesewax is FDA approved for use in and around food, it is **made synthetically from petroleum products and information about the product components is lacking**.
- Food grade waxes produced by "green chemistry" utilizing less toxic, energy-saving processes and plant byproducts, should be investigated further before microcrystalline cheesewax is considered for relisting.
- **Soy wax from domestically produced, non-GMO soybean is available** and should be added to the National List as a better alternative to microcrystalline cheesewax.

DISCUSSION

Microcrystalline cheesewax is used to seal the plug or sawdust spawn that is used to inoculate logs for growing mushrooms.[387] It keeps moisture in and insects and other wild fungi out. Some growers also wax the log ends for more moisture retention.[388] According to the 2007 petition, cheesewaxes are FDA approved and are produced as blends of three ingredients: microcrystalline wax (CAS # 64742-42-3), paraffin (CAS # 8002-74-2), and petrolatum (CAS # 8009-03-8).[389]

A rule amendment was published on 2/14/12 in the Federal Register that allows microcrystalline cheesewax for use in log-grown mushroom production. It must be made without either ethylene-propylene co-polymer or synthetic colors.[390] Microcrystalline cheesewax is made synthetically from petroleum products and a major concern of the Crops Subcommittee was the **data gaps in information about the product components**. Additional information was requested on soy wax as an alternative.

A European Commission Report from 1997 notes that because food grade oils and waxes originate from a range of crude oil starting materials, they are complex mixtures with wide variation in composition. They can best be described by their physical properties

---

[387] http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5110806
[388] http://northernwoodlands.org/articles/article/growing_shiitake_mushrooms
[389]http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5067031&acct=nopgeninfo
[390] http://www.gpo.gov/fdsys/pkg/FR-2012-02-14/pdf/2012-2938.pdf; Federal Register, Vol 77, No. 30, Tuesday, Fe. 4, 2012.

(color, melting point, solid/liquid/semi-solid, etc.) since they cannot be precisely chemically characterized like other food additives because each batch is different. A product from one manufacturer can vary over time and products that appear physically similar can differ in their exact chemical constituents.[391] For example, one of the components of cheesewax, petrolatum, is a semi-solid composed of a mixture of hydrocarbons mostly having greater than 25 carbons, while paraffin, another component, is a solid and composed of hydrocarbons having mostly 20 or more carbons.[392, 393]

Alternatives exist

The alternative suggested is soy wax. The majority of soy wax is produced from soy oil by only four producers: Cargill (now doing business as Elevance Renewable Sciences), Bunge Corporation, Archer Daniels Midland (ADM), and Golden Brands. All the wax produced from these manufacturers comes from GMO soy seed farmed with pesticides and insecticides using high intensity conventional farming practices. In order to process the oil into wax, several chemicals are needed including hexane to extract the soy oil from rolled flakes, chlorine bleach to remove color, and a nickel catalyst to hydrogenate the oil to produce wax.[394] However, **soy wax from domestically produced, non-GMO soybean is available and should be added to the National List as a better alternative to microcrystalline cheesewax**. [395,396,397]

Hexane is a neurotoxin that can cause long lasting and sometimes permanent nerve damage. It is highly volatile and the most common exposure route is through inhalation. It can also be absorbed through the skin. Workplace regulations need to be strengthened to protect workers.[398] The Cornucopia Institute's report *Behind the Bean* indicates that many "natural" soy products are manufactured using hexane and that, upon testing, some soy products contain up to ten times the amount of hexane the FDA considers normal.[399] The industry uses vacuum distillation to remove the hexane but trace amounts are likely found in the wax and if so, these amounts could be harmful.[400] In unrelated studies of bioreactors, the fungus *Fusarium solani* has been tested for removal of volatile organic compounds such as hexane. The fungus was shown to

---

391 http://ec.europa.eu/food/fs/sc/scf/reports/scf_reports_37.pdf; Food and Science Techniques: Reports of the Scientific Committee for Food (37th Series), European Commission, Directorate General for Industry, 1997.
392 http://chem.sis.nlm.nih.gov/chemidplus/rn/8009-03-8
393 http://chem.sis.nlm.nih.gov/chemidplus/rn/8002-74-2
394 http://www.alohabay.com/people/What-Chemicals-Are-in-Your-Soy-Candles.html
395 http://www.fungi.com/product-detail/product/sealing-wax-for-plug-spawn-10-pounds.html
396 http://www.sporetradingpost.com/plugs.htm
397 http://www.soya.be/soy-wax-production.php
398 http://www.nrdc.org/health/files/hexane.pdf
399 http://www.cornucopia.org/soysurvey/OrganicSoyReport/behindthebean_color_final.pdf
400 http://www.alohabay.com/people/What-Chemicals-Are-in-Your-Soy-Candles.html

biodegrade gaseous hexane in biofilters.[401] Thus, it is unknown but possible that a fungus such as Shiitake could absorb hexane if it is present.

New experiments are exploring the manufacture of waxes using green chemistry. For example, at York University Green Center of Excellence, waxes have been produced from crop byproducts, wheat and barley straw, timber residues, and grasses. These waxes were produced by using supercritical carbon dioxide that **does not have any solvent residue issues**. The process also uses less energy than traditional methods.[402] Elegance Renewable Sciences, Inc. and Dow Corning have teamed up to produce **soy waxes using green chemistry and are currently used in personal care products**. The production methods may have cost and environmental benefits.[403]

Environmental and health data

The following environmental and health data come from a U.S. EPA hazard characterization technical document that is part of the High Production Volume (HPV) Challenge Program and relate to the three components of microcrystalline wax. The HPV Program is a voluntary program where manufacturers and importers of high volume chemicals (more than 1 million pounds/year manufactured or imported) submit data on 18 internationally agreed to Screening Information Data Set endpoints (SIDS). These endpoints are indictors of potential environmental or human health hazards and include acute toxicity, developmental and reproductive toxicity, ecotoxicity, and environmental fate. The focus of this September 2011 report was Waxes and Related Materials.[404]

---

[401] http://www.ncbi.nlm.nih.gov/pubmed/16646479; Environ Sci Technol. 2006 Apr 1;40(7):2390-5. Gaseous hexane biodegradation by Fusarium solani in two liquid phase packed-bed and stirred-tank bioreactors. Arriaga S1, Muñoz R, Hernández S, Guieysse B, Revah S.

[402] http://phys.org/news/2011-02-green-chemistry-route-zero-waste-production.html Green chemistry offers route towards zero-waste production, February 18, 2011

[403] http://www.elevance.com/media/news-releases/elevance-and-dow-corning-announce-breakthrough-ingredient-to-enhance-performance-in-personal-care-products/; Elevance and Dow Corning Announce Breakthrough Ingredient to Enhance Performance in Personal Care Products, December 8, 2010.

[404]http://www.epa.gov/chemrtk/hpvis/hazchar/Category_Waxes%20and%20Related%20Materials_September_2011.pdf ; US EPA Hazard Characterization Document, September 2011.

Table 4: Comparison of Waxes

	Persistence in the Environment	Bioaccumulation	Biodegradation
Microcrystalline wax (CAS # 64742-42-3)	low to moderate	low	no data
Paraffin (CAS # 8002-74-2)	low	low to high	80% after 28 days (readily biodegradable)
Petrolatum (CAS # 8009-03-8)	low to moderate	low to moderate	no data

Substances in the Waxes and Related Substances category are expected to possess low soil mobility and to be non-toxic to aquatic plants and invertebrates.[405, 406,407]

Human health concerns

Microcrystalline wax: When tested via the oral route in rats, microcrystalline wax (exact identity unknown) had a low acute toxicity. When two different microcrystalline waxes (one clay-treated and one hydrotreated) were tested in a 90-day repeated dose oral exposure (doses were up to approximately 1100 mg/kg body weight per day), no significant effects were observed. Based on this, a "no observed adverse effect level" (NOAEL) was set at 1100 mg/kg body weight per day.

The HPV Challenge Program identified data gaps for the following human health endpoints: reproductive toxicity, developmental toxicity, and genetic toxicity (no data provided). Carcinogenicity was not addressed for this substance.[408]

Paraffin: When paraffin wax (exact identity unknown) was tested via the oral route in rats, it had low acute toxicity. When rats were exposed for 90 days via their diet to hydrotreated paraffin wax, effects on various body organs was found. There were increased organ weights (spleen, liver, and lymph nodes), effects on hematology and clinical chemistry, and histopathology changes including effects on the liver, lymph nodes, small intestine, and heart. These effects occurred at an estimated dose of 110 mg/kg of body weight per day. The "no observed adverse effect level" (NOAEL) was 11 mg/kg of body weight per day. Another study in 2010 looked at the effects of paraffin

405 http://www.ncbi.nlm.nih.gov/pubmed/16646479; Environ Sci Technol. 2006 Apr 1;40(7):2390-5. Gaseous hexane biodegradation by Fusarium solani in two liquid phase packed-bed and stirred-tank bioreactors. Arriaga S1, Muñoz R, Hernández S, Guieysse B, Revah S.

406 http://www.epa.gov/chemrtk/pubs/general/hpvsuplm.pdf

407 http://www.epa.gov/oppt/sf/pubs/ecosar.pdf

408 http://www.ncbi.nlm.nih.gov/pubmed/16646479; Environ Sci Technol. 2006 Apr 1;40(7):2390-5. Gaseous hexane biodegradation by Fusarium solani in two liquid phase packed-bed and stirred-tank bioreactors. Arriaga S1, Muñoz R, Hernández S, Guieysse B, Revah S.

wax on two different rat strains and found that one strain was more sensitive to exposure than the other. For this study, the NOAEL could not be established.

The HPV Challenge Program identified data gaps for the following human health endpoints: reproductive toxicity, developmental toxicity, and genetic toxicity (no data provided). Carcinogenicity was not addressed for this substance.[409]

Petrolatum: A two-year study on rats receiving repeated oral doses of petrolatum (approximately 2500 mg/kg body weight per day) showed no adverse effects.
The HPV Challenge Program identified data gaps for the following human health endpoints: reproductive toxicity, developmental toxicity, and genetic toxicity (no data provided). No evidence of carcinogenicity was observed.[410]

CONCLUSION

The Cornucopia Institute **remains neutral** on the relisting of microcrystalline wax until a more in-depth Technical Report is completed on the current state of food grade waxes produced by green chemistry (currently commercially available) which utilizes less toxic, energy-saving processes, and plant byproducts.

[409] Ibid.
[410] http://www.ncbi.nlm.nih.gov/pubmed/16646479; Environ Sci Technol. 2006 Apr 1;40(7):2390-5. Gaseous hexane biodegradation by Fusarium solani in two liquid phase packed-bed and stirred-tank bioreactors. Arriaga S1, Muñoz R, Hernández S, Guieysse B, Revah S.

LIVESTOCK SUBCOMMITTEE

PROPOSALS

Methionine

Even though The Cornucopia Institute has submitted written testimony on methionine on several occasions, we deem the topic important enough to resubmit updated testimony including some new information we feel warrants consideration by the NOSB.

SUMMARY

The Cornucopia Institute is **neutral** on the Livestock Subcommittee methionine proposal submitted 2/17/15 to amend §205.603(d) to read:

> *DL–Methionine, DL–Methionine—hydroxy analog, and DL–Methionine—hydroxy analog calcium (CAS #'s 59-51-8, 583-91-5, 4857-44-7, and 922-50-9)—for use only in organic poultry production at the following maximum average pounds per ton of 100% synthetic methionine in the diet over the life of the flock:*
> *Laying hens – 2 pounds; Broilers- 2.5 pounds*
> *Turkeys and all other poultry – 3 pounds.*

The Cornucopia Institute remains neutral because adjustment of rations as proposed is not a major factor in the use of synthetic methionine. The main issue we wish to address is discontinuing the use of synthetic methionine by substituting a better diet and different production systems—more consistent with organic philosophy and the expectation of consumers.

We remain supportive of the sunsetting of synthetic methionine sometime in the near future. At this juncture, we believe amending the language as listed above will provide organic poultry producers the interim flexibility needed to adjust their poultry diet according to the species and state of life of the birds. Younger birds need more methionine than older birds. By changing the language to read "over the life of the flock," this would allow producers to make minor methionine dosage adjustments over the life of their birds.

Additionally, The Cornucopia Institute believes that the NOSB should encourage aggressive research on natural sources of methionine, alternative poultry management systems, and breeding for poultry that perform well on less methionine, as the Livestock Subcommittee has suggested with their new resolution (2/17/15) stating:

> ***The National Organic Standards Board is committed to the phase-out of synthetic methionine for organic poultry production****, and encourages*

aggressive industry and independent research on natural alternative sources of methionine, breeding poultry that perform well on less methionine, and management practices for improved poultry animal welfare.

Also setting a firm date for the termination of synthetic methionine would provide incentive for private and public investment in that research.

Rationale:

This substance has been scheduled to sunset many times (2005, 2008, 2010) and is always extended because viable alternatives are purportedly not available. However, some feed mills and poultry scientists argue alternative options exist and that flock management plays a large role as well. In order to encourage the adoption of alternatives to synthetic methionine supplementation, this substance should be allowed to sunset.

DISCUSSION

Methionine is an essential amino acid; therefore, it must be present in poultry diets to maintain optimal bird health. Additionally, if the amino acids supplied are not in the proper, or ideal, ratio in relation to the needs of the animal, then amino acids in excess of the least limiting amino acid will be deaminated (when amino acids are broken down if there is an excess of protein intake) and likely used as a source of energy rather than towards body protein synthesis. This breakdown of amino acids will also result in higher nitrogenous excretions.[411]

This proposal allows farmers to supplement their poultry feed with minimal amounts of synthetic methionine if their flock requires supplementation. This proposal suggests that poultry require synthetic methionine, but that is only partially true. When poultry are raised on a restricted diet of corn and soybeans <u>without access to meat scraps, insects, or foraging outdoors</u>, methionine supplementation is indeed necessary because the animals are not getting enough naturally occurring methionine from their diet. Also, when they are stocked at very high densities, the birds exhibit more stress and feather-pecking and need more methionine as a result.

Please note: Although the industry has argued the necessity of synthetic methionine supplementation, on the basis of animal welfare considerations, the material clearly acts as a production aid, increasing annual egg output, and its role in that capacity has been grossly underplayed in the arguments by the egg industry for its continued use.

According to the current Technical Report, methionine is considered to be the first limiting amino acid in corn-soy poultry diets. However, poultry do not need to be raised on such a restricted diet. A balanced, diverse diet for omnivorous poultry includes fresh

[411] Todd J. Applegate. 2008. Protein and Amino Acid Requirements for Poultry. USDA NRCS publication.

green plants, insects, worms, and other animal protein. This is what poultry have evolved to eat and what they would eat in the wild to obtain all of their essential nutrients and amino acids.

Both the proposal and the Technical Report failed to fully consider the benefits of a healthy, diverse natural diet for poultry—and a management approach, including liberal access to high-quality outdoor space, consistent with the overall philosophy of organics.

Poultry have been domesticated for thousands of years. During most of that time, farmers and homesteaders have maintained healthy poultry without synthetic methionine. Surely, modern organic growers can do the same. Commercial-scale, conventional poultry are raised with the addition of synthetic nutrients because their diets are uniform and restricted, and the birds are, generally, confined at very high stocking densities without outdoor access. In organic production, diversified diets and management practices should be the primary approach of ensuring adequate nutrition for livestock since the principles of organic state that it is a system based on ecology, not input substitution.

Human health concerns

There are some studies, referenced by Dr. Walter Goldstein in his written comments, that indicate the supplementation of methionine may increase the production of growth hormones in the birds, such as insulin-like growth factor 1 (IGF-1). We found some studies that indicated an increase of IGF-1 and Growth Hormone Receptor (GHR) in the livers of birds and some found it in the meat tissue.

For example, Del Vesco et al. found that the "Addition of methionine improved animal performance by stimulating synthesis and release of growth factor."[412] IGF-1 MRNA expression, and Growth Hormone Receptor RNA were significantly higher in the liver with addition of synthetic methionine, and IGF-1 mRNA showed a similar, though statistically non-significant increase in muscle tissue. Dozier et al.[413] found that amino acids, especially methionine, stimulate the IGF-1 signaling pathway with causes muscle growth. Whether or not synthetic methionine or natural forms of methionine differ in creating this hormonal response (i.e., IGF-1 or GHR) needs more research.

According to Dr. Goldstein, first natural methionine, being bound as a component of protein, must go through a complex enzymatic and microbial digestive process before it can be assimilated across the small intestine whereas synthetic methionine does not have to.

---

[412] Del Vesco, A.P., E. Gasparino, A.R. Oliveira Neto, S.E.F. Gulmaraes, S.M.M. Marcato, and D.M. Voltolini. 2013. Dietary methionine effects on IGF-1 and GHR mRNA expression in broilers. Genetics and Molecular Research 12(4):6414-6423.

[413] Dozier III, W.A., M.T. Kidd, A. Corzo. 2008. Dietary Amino Acid Responses of Broiler Chickens. Journal of Applied Poultry Research. 17(1): 157-167.

D-methionine is rarely ever found in natural systems. Once across the intestinal barrier, chickens convert the D-methionine to L-methionine enzymatically in their liver or kidney and then use it.[414] Whether or not synthetic methionine or natural forms of methionine differ in creating IGF-1 or GHR response needs more research. However, Dr. Goldstein's point is that the natural and synthetic substances induce different activities in the body of the bird, and there may be a lot in this regard that, currently, remains unknown. Pertinent to the knowledge gap is that different forms of synthetic methionine may differ, at times strongly, in their effects on increasing IGF-1 levels in poultry.[415],[416]

Why the concerns about IGF-1 levels in poultry tissues? There have been numerous studies that have found linkages between IFG-1 levels in human plasma and an elevated risk for prostate, breast, colorectal, and lung cancer.[417]

If synthetic or excessive natural sources of methionine are added to the poultry diet, might it be generating health problems for those that consume those poultry products? Unfortunately, the Technical Reports have not explored this issue.

Alternatives exist

There are many natural sources of methionine. Indeed, feed mills already blend in varying quantities of these natural sources of methionine (MET) to meet the requirements of the birds, in addition to the small amounts of synthetic methionine that they add.

In the table below, you can see various organic feed formulations with their minimum levels of methionine according to their guaranteed feed tags. Under the current language, only 2 pounds of synthetic methionine can be used per ton, regardless of the poultry species or its stage of life. That amounts to 0.1% of the feed ingredients by weight. Yet, as the table shows, most feed tags show a higher minimum level of methionine, which means that other ingredients in the feed are supplying some of the overall methionine percentage. In most cases, the other ingredients supply between two-thirds to three-fourths of the overall methionine percentage. All of the following

[414] Goodson, J., J. Thomson, and A. Helmbrecht. 2012. Feeding value of L-Methionine versus DL-Methionine. Evonic Industries. 6 pp.

[415] Willemsen ,H., Q. Swennen , N. Everaert , P.-A. Geraert , Y. Mercier , A. Stinckens , E. Decuypere , and J. Buyse. 2011. Effects of dietary supplementation of methionine and its hydroxy analog DL-2-hydroxy-4-methylthiobutanoic acid on growth performance, plasma hormone levels, and the redox status of broiler chickens exposed to high temperatures. Poultry Science 90: 2311–2320

[416] Del Vesco, A.P., E. Gasparino, A.R. Oliveira Neto, S.E.F. Gulmaraes, S.M.M. Marcato, and D.M. Voltolini. 2013. Dietary methionine effects on IGF-1 and GHR mRNA expression in broilers. Genetics and Molecular Research 12(4):6414-6423.

[417] Renehan, A.G., M. Zwahlen, C. Minder, S.T. O'Dwyer, S.M. Shalet, M. Egger. (2004). Insulin-like growth factor (IGF)-I, IGF binding protein-3, and cancer risk: systematic review and meta-regression analysis. The Lancet. 363: 1346-1353.

feeds use synthetic dl-methionine in the ration except for two formulations by Coyote Creek Feed Mill, noted below.

Table 5: Comparison of Methionine in Feed Formulations

Feed Mill	Formulation	Minimum methionine %
Scratch N Peck Feeds	Soy Free Broiler	Methionine .35%
Scratch N Peck Feeds	Soy Free Layer	Methionine .30%
Green Mountain Feeds	Soy Free Layer	Methionine .30%
Green Mountain Feeds	Regular Layer	Methionine .30%
Green Mountain Feeds	Turkey Starter	Methionine .5%
Green Mountain Feeds	Turkey Grower	Methionine .4%
Nature's Best	Broiler Grower	Methionine .33%
Nature's Best	Layer Pellet	Methionine .28%
Nature's Best	Turkey Starter	Methionine .48%
Nature's Best	Turkey Grower	Methionine .35%
Hiland Naturals	Broiler Grower	Methionine .25%
Hiland Naturals	Layer Pellet	Methionine .25%
Coyote Creek	Soy Free Layer (no synth methionine added)	Methionine .30%
Coyote Creek	Regular Layer	Methionine .38%
Coyote Creek	Broiler Grower (no synth methionine added)	Methionine .37%
Coyote Creek	Broiler Starter	Methionine .38%
Coyote Creek	Turkey Starter	Methionine .37%
Coyote Creek	Turkey Grower	Methionine .35%

Although this is not a complete national survey of commercially available organic poultry feeds, it is helpful to illustrate the average percentages for different species and stage of life based on the table above:

Broiler starter: .38% minimum methionine
Broiler grower: .325% minimum methionine
Layer rations (including soy-free formulations): .30%
Turkey starter: .45%
Turkey grower: .37%

The National Research Council recommends the following levels of methionine[418]:

Broiler starter: .50% (0-3 weeks)
Broiler grower: .38% (3-6 weeks)
Layer rations (once laying): .22%

One can see that the current allowed rate of 2 pounds per ton (.1% by weight) synthetic methionine is then only a third or a quarter of the total methionine percentages provided in these organic feed formulas above and the NRC recommendations. The

[418] National Research Council: Nutrient Requirements for Poultry (9th Edition), 1994.

majority is actually being provided by the naturally occurring methionine present in soy, fishmeal, crab meal, and other ingredients.

It can also be inferred from the table above that layers have the lowest methionine needs (at least in their adult stages), followed by broilers then turkeys. Applying a 2 pounds per ton rate to all poultry species does not represent the needs of each species. The new proposal will allow for variations to occur, with layers still getting 2 pounds (.1% MIN methionine), broilers getting 2.5 pounds (.125% MIN methionine), and turkeys/other poultry species getting 3 pounds (.15% MIN methionine). This is only a third or less of these species' total methionine needs, so there will still be a very strong incentive to utilize natural sources of methionine and continue to research new ones.

The amount of total sulfur amino acids (MET + CYS) in feedstuffs should be considered instead of mainly focusing on MET. If cysteine (CYS) is inadequate, some of the MET will be used to satisfy that requirement.[419] Some high MET/CYS amino acid feedstuffs include: high-methionine corn, fishmeal, crab meal, milk powder, meat and bone meal, potato meal, black soldier fly larvae, algae, sesame meal, corn gluten meal, sunflower meal, soybean meal, and brewer's yeast. However, with every feed ingredient, there are nutrients and anti-nutrients or other tradeoffs to consider. It is never a simple formula.

Some of the challenges with these alternative feeds include:

- Limited organic supply or currently not available in organic form (such as high-methionine corn, corn gluten meal, or potato meal);
- Based on unsustainable supply (often the case with fishmeals such as wild-caught menhaden, sardines, or anchovies or conventionally farmed fish like tilapia);
- Utilize GMO ingredients (farmed fish or some algae processes);
- Use non-organic compliant preservatives (ethoxyquin in crabmeal);
- Chemical solvents in extraction (such as hexane in oilseed crops);
- Can impart bad flavors in eggs or meat (such as with fishmeal, crabmeal, or flax);
- Low digestibility (i.e., sesame seed meal, even though high in MET, is not in a digestible form);
- Can cause an increase in nitrogen levels (such as adding more soy or high protein corn to provide higher levels of natural methionine) such that the excreta are higher in volatile ammonia and nitrate nitrogen, both potential pollutants; and
- Not yet approved by FDA for poultry rations (such as black soldier fly meal).

A few organic feed mills contacted by The Cornucopia Institute stated that they utilize some of these alternative sources of methionine in their feed blends, but that supplies of alternatives to synthetic methionine are limited and costly.

[419] Fanatico, A. 2010. Organic Poultry Production: Providing Adequate Methionine. NCAT. 20 pp.

One stated that if synthetic methionine is eventually eliminated, the largest vertically integrated egg and poultry producers would likely snatch up these limited natural methionine sources for their corporate-owned feed mills and little would be left for the independent feed mills and smaller producers.

Price would also go up as demand for limited supplies goes up. Conversely, it would likely stimulate demand for increasing the production of these alternatives. This has already happened in a similar vein with the increasing demand for alternatives to soy protein in poultry feed. Crops like sesame and camelina are in more demand and production has increased to meet that demand over the last few years. The use of unsustainable wild-caught fishmeal has also increased in soy-free feeds, but it is a source of natural methionine and other essential amino acids.

Vegetarian vs. omnivore

Simply replacing synthetic methionine with alternative plant-based feeds overlooks the natural feeding habits of poultry. Just because some consumers have come to expect organic poultry to be produced with "vegetarian-fed" does not mean that poultry should be forced, unnaturally, to be vegetarians.

Vegetarian-fed is more of a marketing-oriented approach than something that consumers demand, especially if they are informed about the true nature of poultry (and the organic regulations require promoting the natural instinctive behavior of livestock).

Indeed, the Livestock Subcommittee issued a discussion document on 8/21/2013 about allowing omnivorous species like poultry and swine to be allowed omnivorous diets through the addition of <u>organically certified</u> meat-scraps or animal byproducts in their feed. Sadly, that discussion document went nowhere at the time.

Currently seafood and insects are the only approved animal products allowed in organic poultry feed, but they have their limitations, as described above. If organic poultry producers could utilize certified organic blood meal, bone meal, fresh and dried meat meal, they could likely satisfy all of their methionine needs, as well as a percentage of their protein and fat needs. This would also help develop a market for those animal byproducts that may not be fully utilized. It could help organic slaughterhouses and meat marketers operate more profitably if they had markets for all of the lower-value animal parts.

If these animal-derived products were properly cooked and/or dried, they would be free of pathogens and safe for feeding to poultry (or swine). Some feed mills interviewed reported that they would not want to handle mammalian animal products in their mills due to concerns about BSE contamination and the need to maintain some of their buyers' "vegetarian-fed" marketing claims. Other feed mills are already using fishmeal and crab meal, thus adding other animal-based ingredients would likely not be problematic.

It should be noted that the "consumer expectations" being referenced have nothing to do with organic production per se but rather the ability to market eggs as produced with "vegetarian feed," an unnatural diet for omnivorous poultry. However, we understand that under current NOP rules, the feeding of mammalian proteins to poultry is prohibited and thus the genesis of the statement "vegetarian-fed" as a way for producers to explain that prohibition.

Aquatic animals such as fish and crabs have always been allowed as a poultry feed, but research has shown that their inclusion above 5% of the diet imparts off-flavors. Many poultry producers have chosen to not use fish or crab meal at all and stick to completely plant-based nutrients, with the exception of synthetically derived methionine (the cheaper alternative).

Foraging for methionine?

In nature, poultry species forage outdoors, looking for insects, grubs, and soil-dwelling invertebrates (fulfilling their needs in methionine), as well as fresh green plants and seeds. They also eat small animals such as rodents, amphibians, and reptiles when they have the opportunity. In order for poultry to better obtain adequate levels of nutrients and essential amino acids such as methionine from their natural diet, it would be necessary to allow them to forage outdoors on pasture. This management approach would provide a natural source of necessary nutrients and a viable alternative to synthetic methionine, at least for part of the year. It would also cut down on aggressive behavior—one of the prime justifications that industry representatives make for continued synthetic refining supplementation.

The Livestock Subcommittee proposal goes on to state:

> *Pasture may provide some supplementation during the right conditions, but is certainly not a dependable solution.*

For thousands of years, pasture has been a dependable solution. Access to the outdoors, including access to soil and vegetation, allows chickens to incorporate in their diets all needed nutrients as long as their stocking densities are kept at reasonable levels. Understandably, severe weather may periodically prevent pasture access at times during the year, but pasture access is essential to the raising healthy animals and should not be dismissed as in the above quote.

Allowing birds to have adequate access to pasture will allow them to meet much of their methionine needs. This was verified in an experiment conducted by poultry scientist Dr. Joe Moritz of West Virginia University; he concluded that growth impairments and compensatory feed intake associated with marginal methionine deficiency (in birds not supplemented with synthetic methionine) were largely overcome by foraging.

However, fall pastures had lower levels of methionine and therefore pasturing will require some level of supplementation to provide year-round methionine needs.[420] His study did not look at winter or spring pastures, only summer and fall. It can logically be assumed that winter pastures would be low in methionine as well. Spring pastures, however, may have sufficient new plant growth to so that adequate levels of methionine are available in the plants. Further research would benefit the industry's understanding of this option.

While it might not be possible for densely packed poultry barns with 10,000 to 100,000 birds to provide enough pasture for the birds to meet their methionine requirements, organic operations with lower stocking densities using intensive rotational pasturing would likely provide a large portion of their poultry's methionine needs for at least a good part of the year.

There is a blurry line between what is necessary for poultry health and well-being and what is, essentially, being used as a "growth and production aid" when it comes to synthetic methionine.

Many other countries, including those in the European Union, limit poultry stocking densities both indoors and outdoors. EU organic standards require 43 square feet of space per bird outdoors, which is equivalent to just around 1,000 birds per acre. This is much lower than the stocking densities in current use by some U.S. organic poultry producers, who may provide only a very small fenced-in yard which 25,000 birds are supposed to share (obviously not all birds can go outside at the same time, and the overall densities are high).

This makes the value of the available outdoor area virtually useless because there is little to no vegetation, bugs, or worms due to the high stocking density. In fact, the outdoor area is probably so covered with manure that it not only is useless for the birds' diet, it is actually just as detrimental to their overall health and well-being, is inside the buildings, due to the amount of manure caking the ground.

That is not a rationale against outdoor access; rather, it is a call to provide good quality pastures with meaningful access with the **appropriate stocking density of birds**, and adequate management, so that the pasture remains healthy. Under these conditions, the birds do best and are able to meet a significant portion of their methionine needs through foraging.

EU organic poultry standards now include a nitrogen loading rule to better determine appropriate stocking densities insuring that outdoor areas do not accumulate unhealthy levels of manure and to minimize the possibility of nutrient pollution via runoffs or ammonia vaporization.

---

[420] Moritz, J. S., et al. "Synthetic methionine and feed restriction effects on performance and meat quality of organically reared broiler chickens." *The Journal of Applied Poultry Research* 14.3 (2005): 521-535.

Letting poultry forage on pasture allow them to hunt and eat insects and other invertebrates, which provides the birds with animal protein containing methionine.[421,422] This also meets the regulatory requirement for promoting livestock's natural instinctive behaviors.

This thesis is not strictly based on academic research; some poultry producers have been able to raise chickens without synthetic methionine. The practices include adequate access to pasture of reasonable quality, natural supplements of organic whole wheat, organic whole oats, alfalfa meal, sunflower meal, and fishmeal.[423] Approximately 16% of the organic egg farmers we surveyed in 2014 (with flocks ranging from 100 up to 20,000 per barn) do not use synthetic methionine in their layer ration. Although this certainly is not a large percentage, it does illustrate that it is possible for commercial producers to implement viable alternatives to densely packed poultry barns with sorely inadequate outdoors access—and calls into question the essentiality of synthetic methionine use.

Despite all the arguments made above for the continued use of a small percentage of synthetic methionine, there **is a need to create a more holistic organic production system** that minimizes the need for it. These practices, all consistent with the organic philosophy and with OFPA itself, may include:

- Access to healthy, growing pasture, not just a porch;
- Stocking densities that allow pastures to maintain vegetative cover and natural biodiversity (insects, worms, etc.) to thrive;
- Requiring young pullets to have access to the outdoors, not just laying hens;
- Sufficient "popholes" in the chicken house to encourage outdoor foraging;
- Setting up some feeding stations with water and shade outside to encourage foraging;
- The use of slower-growing or heritage chicken breeds that are capable of superior foraging;
- Management practices that include opening doors as much as possible and rotating/resting fields to allow pastures to regenerate;
- A varied diet of diverse, nutritious foods, not just corn/soy; and
- Natural supplements that could include herbal methionine or non-GMO fermented methionine (two new products that may take a few years to be approved in the U.S.).

CONCLUSION

Due to concerns that this synthetic material is being used as a production aid instead of providing more legitimate outdoor access, pasture, diverse diets, appropriate stocking

---

[421] Fanatico, A. 2010. Organic Poultry Production: Providing Adequate Methionine. NCAT. 20 pp.
[422] Spencer, T. 2013. Pastured Poultry Nutrition and Forages. NCAT. 20 pp.
[423] Hungerford, C. 2007. There's a synthetic in my organic chicken. The New Farm. Retrieved July 7, 2011 from 1050 http://newfarm.rodaleinstitute.org/columns/org_news/2005/0405/methionine_print.shtml

densities, and slower-growing breeds and because there may be a connection between synthetic methionine supplementation and increased IGF-1 formation in the poultry tissues, The Cornucopia Institute **remains neutral on the new Livestock Subcommittee proposal—and continues to support pressure to remove synthetic methionine, as an approved feed supplement, at the earliest possible, practicable juncture.** There are just too many outstanding concerns for this substance to remain on the National List although instant removal would have widespread impacts, at every scale, within the organic egg industry.

Therefore, we strongly support aggressive research into the alternatives to synthetic methionine and a firm expiration date.

Acidified Sodium Chlorite

SUMMARY

The Cornucopia Institute is **neutral** on the petition to list acidified sodium chlorite to §205.603(a) and §205.603(b) of the National List annotated as follows: Acidified Sodium Chlorite, Allowed for use on organic livestock as a pre and post teat dip treatment, acidified with lactic acid or other GRAS acid.

As we articulate below, acidified sodium chlorite (ASC) appears to have promising utility for organic dairy producers. However, scientific data is lacking on potential detectable residues in milk (as are present with many teat dips) and any associated impacts on human health.
In addition, any potential approved use, or restricted use, should take into consideration the environmental liabilities as have been conveyed in the written comments from Beyond Pesticides regarding chlorine-based compounds.

Rationale:

- The Livestock Subcommittee recently voted to support this material on 1/27/2015.
- Acidified sodium chlorite is very effective against various mastitis-causing organisms and is a useful tool to have for organic dairy producers.
- Although alternatives exist, it is important to have several antimicrobial compounds like ASC to use in rotation so that microbial resistance is less likely to occur.
- The production of chlorine-based compounds has serious environmental impacts that must be considered.
- More research is needed on any potential residue products that could end up in the milk.

DISCUSSION

Acidified sodium chlorite contains various chlorine compounds, which act as a disinfectant in a solution at very low pH, approximately 2.3 – 3.2. When acidified with citric acid, ASC is allowed in organic handling as an antimicrobial food treatment for organic foods.

The current petition requests to add ASC as an allowed synthetic in organic livestock production for use as a disinfectant and topical treatment teat dip for dairy animals.

This material is not widely supported by the organic industry because it has not been approved yet so there is little to no established experience with this substance in organic dairy. The TR states:

> *International regulations regarding the use of acidified sodium chlorite (ASC) solutions in organic agricultural production, processing, and handling are lacking. However, a number of international inspection agencies and risk assessment organizations have approved the application of ASC solutions in the processing/handling of fruits, vegetables, and meat products*" (lines 176-179)[424]

It should also be pointed out that ASC is also listed on the National List at §205.605b for use as an antimicrobial food treatment when acidified with citric acid (TR lines 167-168). It is also widely used in the U.S. poultry industry to disinfect poultry carcasses and is approved by the USDA Food Safety Inspection Service for direct contact on meat.

The Livestock Subcommittee recently changed its stance on this material after considering the need for multiple antimicrobial teat dips in order to prevent resistance issues that could occur from utilizing one of the alternative products. Research has also shown this material to be highly effective on several mastitis-causing organisms such as *Staph* and *Strep* species.

Environmental considerations

The production of ASC begins with its feedstocks, namely sodium chlorite and an activating acid, such as lactic acid. The solution is made on site right before use. Sodium chlorite is produced from chlorine dioxide, which is then absorbed into an alkaline solution and reduced with hydrogen peroxide (H_2O_2), yielding sodium chlorite. The production of chlorine dioxide has some environmental impacts, yet it is a less toxic chlorinated compound than chlorine or hypochlorites because it does not yield toxic byproducts such as trihalomethanes.

---

[424] Pesticide Research Institute. (2013). Acidified Sodium Chlorite (Livestock) Technical Evaluation Report.

According to the TR (lines 321-327): As inorganic oxychlorine compounds, acidified sodium chlorite (ASC) and chlorine dioxide have the potential to form toxic, mutagenic, and carcinogenic by-products such as halogenated organics and semicarbazides. However, in contrast to stronger oxidizing agents such as sodium hypochlorite, ASC does not lead to the formation of halogenated organic compounds.

The European Food Safety Authority (EFSA) concluded that studies examining the possibility of reaction products provided no evidence of halomethane formation in water treated with chlorine dioxide. In addition, the report states that no chlorinated organics or semicarbazides have been detected (limit of detection = 1 pg/kg) after treatment by immersion of poultry carcasses in ASC[425]

Human health considerations

According to the TR, sodium chlorite is extremely destructive to the tissues of the mucous membranes and upper respiratory tract, and will burn the skin upon dermal exposure. Likewise, gaseous chlorine dioxide is highly irritating to skin and mucous membranes of the respiratory tract.[426] Like any livestock chemicals, proper protective gear and safe operating procedures must be followed to limit occupational hazards.

According to the MSDS from a manufacturer of ASC, skin eruptions may occur after direct contact, and fumes from ASC can cause respiratory problems.[427] Other citations in the TR verify the irritation to skin and respiratory systems that can be caused by ASC.[428] Since this substance is designed to be repeatedly applied to the skin (of cows), there seems a likelihood of irritation.

However, other organically approved teat dips, such as hydrogen peroxide and chlorhexidine, can also cause skin and lung irritation in humans and occasionally irritate the skin of the cows, especially if an emollient is not included in the formulation. Most teat dips, including ASC, use added emollients to avoid irrigating the teat skin.

One concern with any pre-milking teat dip is the issue of potential residues that may end up in the milk. Those residues can leave an off-taste or could even be toxic at certain levels. Chlorhexidane and iodine have all been found to leave residues in the milk, depending on their concentrations and the methods of application and clean-off of the antiseptics.[429] According to the Technical Report (lines 355-356), acidified sodium

---

[425] EFSA (European Food Safety Authority). 2005. Treatment of Poultry Carcasses with Chlorine Dioxide, Acidified Sodium Chlorite, Trisodium Phosphate and Peroxyacids – Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food. *The EFSA Journal*. 297: 1–27.
[426] Ibid.
[427] MSDS Acidified Sodium chlorite. GO2 International. Downloaded on Sept. 12, 2013 from http://www.go2intl.com/pdfs/SAF004en.pdf
[428] Pesticide Research Institute. (2013). Acidified Sodium Chlorite Technical Evaluation Report. Lines 472-483.
[429] Castro S.I.B., R. Berthiaume, A. Robichaud, and P. Lacasse. (2012). Effects of iodine intake and teat-dipping practices on milk iodine concentrations in dairy cows

chlorite breaks down into chlorine dioxide and chlorite; the manufacturer's literature claims that these metabolites are natural compounds.[430]

<u>No scientific papers could be found that explore the subject of ASC residues in milk</u>, probably because it is a relatively new antimicrobial for teat dipping. This is one area of potential concern.

Regardless of the antiseptic used, proper pre-milking teat cleansing procedures should be followed, including 1) pre-cleaning of teats as necessary to remove any mud/manure/etc., 2) forestripping, 3) dipping with a proven germicidal pre-dip product, 4) allowing the recommended contact time (15-30 seconds), 5) drying each teat thoroughly with a single service paper towel or laundered cloth towel to remove surplus germicidal product, microorganisms, and organic material, and 6) attaching teat cups to the dry udder.[431]

Alternatives

Management practices to prevent mastitis include proper milking technique, adequately functioning milking equipment, dry cow therapy, prompt antibiotic treatment, or alternative treatments, of clinical cases (and removal from organic herd if antibiotics are necessary), culling chronically infected cows, keeping animals in a clean dry environment and ensuring a healthy balanced diet.[432] However, research has demonstrated that pre- and post-milking teat dips are "the most effective procedures for preventing (…) infections in dairy cows."[433]

Alternative materials listed in the TR include natural substances such as vinegar (acetic acid), tea tree oil, lactic acid, and synthetic substances such as hydrogen peroxide, iodine, the alcohols ethanol and isopropanol, glycerin, and chlorhexidine.[434] However, isopropanol isn't listed for topical use, so it probably cannot be used as a teat dip. Chlorhexidine can only be used with a veterinary directive, according to its NOP listing. It is supposed to be used only as a last resort substance.

There is no discussion in the TR as to the efficacy of these alternatives, whether or not they irritate the skin of the cow, or if their use results in unpleasant or unacceptable residues in milk (such as iodine), all issues that must be taken into consideration. Below is a table comparing the antimicrobial efficacy as a pre- or post-milking teat dips of a few of these materials:

Journal of Dairy Science. 95:1: 213-220.

[430] http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5108539

[431] Nickerson, Stephen C. (2001). Choosing the Best Teat Dip for Mastitis Control and Milk Quality. *NMC-PDPW Milk Quality Conference Proceedings*, April.

[432] Ibid.

[433] Ibid.

[434] Pesticide Research Institute. (2013). Acidified Sodium Chlorite Technical Evaluation Report. Lines 515-539.

Table 6: Comparison of NOP-approved Teat Dips to the Proposed NOP Teat Dip ASC

	Description*	Post-milking: significant efficacy against**	Pre-milking: significant efficacy against**
Iodine (including concentrations of 0.05% to 1.0%)	Broad spectrum germicide effective against all mastitis-causing bacteria, as well as fungi, viruses, and bacterial spores	*S. aureus, S. agalactiae, C. bovis, Staph. species, other Streptococci*	Environmental pathogens, major pathogens, Gram-negative bacteria
Chlorhexidine (including compounds: digluconate, gluconate, and glycerin)	Rapidly acting, nonirritating germicide effective against most Gram-positive and -negative bacteria, as well as some viruses	*S. uberis, C. bovis, Staph. species, S. aureus, S. agalactiae, E. coli, gram-positive bacilli*	Major pathogens, *Staph*. species
Hydrogen Peroxide	Broad spectrum germicide effective against most mastitis-causing bacteria. Even more effective if combined with lactic acid.	not significantly different from control	NA
Proposed: Acidified sodium chlorite (containing lactic or mandelic acid)	Broad spectrum germicide effective against Gram-positive and -negative bacteria, as well as molds, yeasts, and viruses	*S. aureus, S. dyscalactiae, S. agalactiae,* Major pathogens	*S. uberis,*

* From "Choosing the Best Teat Dip for Mastitis Control and Milk Quality" by Stephen Nickerson
** From the National Mastitis Council's Summary of Peer-Reviewed Publications on Efficacy of Pre-milking and Post-milking Teat Disinfectants Published since 1980 (2009 revision)

Antimicrobial resistance?

Mastitis-causing pathogens may become less susceptible to biocides and antiseptics, just like pathogens are becoming resistant to certain antibiotics. This is a problematic issue that warrants considerably more research. However, antiseptics have broader spectrums of antimicrobial activity than antibiotics with a much lower development risk of bacterial resistance selection. Antiseptics are therefore appropriate alternatives to antibiotics for the prevention and management of localized superficial skin infections such as those found on some cow teats.

The use of biocides/antiseptics can select for resistance to therapeutic antimicrobials in four different ways[435]:

1) Cross-resistance: (i) selection for genes encoding resistance to both the biocidal substance and one or more therapeutic antimicrobial classes or (ii) change the physiological response of the bacterium to become less susceptible to both the biocidal substance and the therapeutic antimicrobial agents.
2) Co-resistance: selection for clones or mobile elements also carrying antimicrobial resistance.

[435] EFSA Panel on Biological Hazards. (2008). Assessment of the possible effect of the four antimicrobial treatment substances on the emergence of antimicrobial resistance. *The EFSA Journal.* 659: 1-26.

3) Indirectly select for clones that are resistant to therapeutic antimicrobials.
4) Enhance DNA uptake by (e.g.) activating a SOS response in bacteria.

Because of the mode of action of halogenated compounds, widespread and extended use of iodine is not associated with the selection of resistant bacterial strains. Iodine has the broadest spectrum of antimicrobial activity of the available antiseptics, and has a rapid and persistent microbicidal effect.[436] However, sublethal doses may lead to resistance problems. Also, dirty teats limit the effectiveness of iodophors and may enable some pathogens to survive.

There are an increasing number of prevalence studies that report reduced levels of pathogen susceptibility to chlorhexidine, with emphasis on the susceptibility of MRSA (a form of Staph). Clinical use of chlorhexidine will continue to increase and it will be important to be alert to the possibility that this may lead to the emergence of new clones with reduced susceptibility. Indiscriminate chlorhexidine use in the absence of efficacy data should be discouraged[437] and is a good rationale to limit its use in organic dairy production.

No literature could be found on microbial resistance to hydrogen peroxide.

At this time, there is no indication that the use of acidified sodium chlorite could support the spread of resistance to therapeutic antimicrobials by direct selection, although the creation of resistance may be possible by indirect selection.[438] According to the TR (lines 371-374) the oxidative mechanism of oxychlorines as antimicrobial agents (e.g., ASC, chlorite, chlorine dioxide) does not generate resistance in microorganisms.

CONCLUSION

Due to its efficacy as a topical disinfectant in livestock, particularly as a teat dip to control mastitis-causing pathogens, ASC appears to be a valuable tool to add to organic livestock producers' toolkits. As a teat dip in particular, it appears to have excellent antimicrobial properties. It also does not appear to lead to any microbial resistance issues (at least not yet), which some of the other organically approved teat dips can generate. In order to prevent the development of microbial resistance to antiseptics such as ASC, it is important to utilize proper handling practices and to have the choice of several different antiseptic materials for alternate use. However, scientific data is lacking on potential detectable residues in milk and any associated impacts on human health. Likewise, there are serious environmental challenges with the manufacturing of chlorine-based compounds that must be taken into account. Therefore, The Cornucopia Institute is **neutral on the listing of acidified sodium chlorite on the National List**.

---

[436] Lachapelle L.M., O. Castel, A. F. Casado, B. Leroy, G. Micali, D. Tennstedt, and J. Lambert. (2013). Antiseptics in the era of bacterial resistance: a focus on povidone iodine. *Clinical Practice*. 10:5: 579-592.
[437] 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.*
[438] EFSA Panel on Biological Hazards. (2008). Assessment of the possible effect of the four antimicrobial treatment substances on the emergence of antimicrobial resistance. *The EFSA Journal.* 659: 1-26.

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 (warts, hoof rot, 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.[439]

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 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.

---

[439] 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.

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.[440,441] 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.[442]

In an Oregon dairy farm study, soil samples were taken up to 15 inches deep to analyze the zinc and copper concentrations.[443] These farms used both zinc and copper sulfate footbaths and discarded that footbath solution into the manure lagoons. That manure

---

440 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.

441 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.

442 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.

443 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.

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 (2800 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 $CuSO_4$ (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.[444],[445]

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.[446] Powdered zinc sulfate may cause eye, skin, respiratory tract, and digestive tract irritation. Appropriate personal protective equipment is required for 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

---

[444] Ibid.

[445] 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 ($ZnSO_4 \cdot 7H_2O$). *Mineralogical Magazine*, Vol. 69:3, pp. 259-271.

[446] Environmental Protection Agency—EPA (1992) Zinc Salts—Reregistration Eligibility Document, EPA-738-F-92-007.

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.[447] 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.[448]

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.[449] 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 plus creosote in kerosene and creosote.[450],[451],[452] The

---

[447] Schivera, D. (2014) Raising organic livestock in Maine: MOFGA accepted health practices, products and ingredients, Maine Organic Farmers and Gardeners Association, Fact Sheets.
[448] 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.
[449] 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.
[450] Murnane, D. (1933) Footrot in sheep, *Journal Counc. Sci. Ind. Res.,* 6, pp. 252-259.

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.[453],[454]

Preliminary results of Cornucopia's Certified Organic Livestock Producer Survey

Cornucopia sent out a survey in late March 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 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

---

[451] Cross, R.F. (1978) Response of sheep to various topical, oral and parenteral treatments for footrot. *J. Am. Vet Assoc*., 173, pp. 1569-1570.
[452] 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.
[453] USDA AMS Technical Review: Zinc Sulfate. 2015
[454] Sullivan, Hilary M. (2005). Hairy Foot Warts. New Mexico State University Extension Guide B-122.

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.

DISCUSSION DOCUMENT

Aquaculture

The discussion document "National Organic Standards Board Livestock Subcommittee Aquaculture Materials Review Update Report February 2015" mentioned that, "No one from industry or the general public came to the meeting [Spring 2014] or provided oral testimony, which made it difficult for the NOSB to understand the potential market demand for any of the materials petitioned." However, this is simply not the case. If this discussion document is supposed to serve as a review of the history of aquaculture regulations in the National Organic Program, it would seem that including the testimony of the following 10 individuals that spoke on aquaculture issues would be important. Six work for non-profit public interest groups, two work for organic certifiers, and two are unaffiliated citizens who traveled all the way to San Antonio, Texas, to speak on this important subject. That is both **industry** and the **general public** making their voices heard.

A short summary of the opinions voiced by individuals at the Spring 2014 NOSB meeting follows:

- **Urvashi Rangan**, Director of Consumer Safety & Sustainability, Consumers Union
  The NOSB should not be approving materials for aquaculture without standards in place.

- **Ramkrishnan Balasubramanian**, Chief Operating Officer, Quality Certification Services
  Aquaponics producers have been waiting over 10 years for standards; in the meantime, other countries are producing organic aquaculture products with

inferior standards. Materials should be approved, even if standards aren't ready, so that when the standards are finally complete there are materials that can be used. CO_2 in particular is important for pH adjustment and is necessary to produce microalgae for feed.

- **Terry Shistar**, Board Member, Beyond Pesticides
  Allowing these materials to be approved without understanding the diversity of aquaculture systems, while overthrowing the democratic process necessary for establishing an appropriate organic policy, would set a bad precedent.

- **JoAnn Baumgartner**, Director, Wild Farm Alliance
  Open ocean aquaculture should not be allowed because pollution and disease, fish escapes, and habitat damage occurring will prohibit fish farmers from meeting the NOP requirements to conserve biodiversity and maintain or improve water quality and wildlife.

- **Lauren Bernick**, Citizen/Consumer, Author of the blog "My Non-Toxic Life"
  Don't approve materials before standards are in place. No open ocean fish farming because of its detrimental impacts on wild species, nutrient pollution, and use of unsustainable fish feeds.

- **Lisa Bunin**, Organic Policy Director, Center for Food Safety
  In the absence of knowledge about the system within which a substance would be added, approving any substance would be arbitrary, capricious, and unlawful. Neither the NOSB nor the NOP has officially evaluated the wide range of aquaculture systems that could be considered organic. The Center for Food Safety has consistently argued that open ocean aquaculture can never be organic.

- **Liana Hoodes**, Executive Director, National Organic Coalition
  Don't approve aquaculture materials without defined system standards.

- **Patty Lovera**, Assistant Director, Food and Water Watch
  Can't approve materials without defined system standards. Open ocean fish farming should not be considered organic. Closed-loop land-based systems perhaps can work in an organic system.

- **Ann Mosness**, Commercial Fisherwoman from Washington
  Approval of organic aquaculture could destroy her business and families that harvest wild seafoods. Open ocean aquaculture produces pollution, pathogens, and parasites that cannot be contained. Raising organic fish in closed systems, such as ponds, may work but still has to be well managed to prevent juvenile fish from escaping.

- **Jim Pierce**, Global Organic Program Manager and Aquaculturist (private), Oregon Tilth

Oregon Tilth endorses the addition of 9 of the 11 materials on the docket for aquatic animal and plant production but has concerns about micronutrients and CO_2. The NOP has written standards [not published], but without a materials list the standards will be useless.

From both written comments and oral testimonies, the overwhelming response to the idea of organic aquaculture is that **individual materials should not be approved without the standards in place** and that **open ocean aquaculture is not consistent with organic principles** and should not be considered as part of the standard. There are many who believe that closed-loop, land-based systems may be possible using organic principles, but more research and more models are needed to prove that system.

During the Spring 2014 NOSB meeting, all of the aquaculture materials (both crops and livestock) were sent back to committee at the request of the full Board. The Livestock Subcommittee is now handling all of the materials, even though some materials are for plant-based aquaculture and not animals. This was done to reduce redundancy because many of these materials will be used for both types of systems and some aquaculture systems grow both plants and animals in the same system.

There continues to be many unanswered questions about these materials that need to be addressed prior to the full Board voting on them. Some of the questions that the Livestock Subcommittee raised include:

Table 7: Concerns about Aquaculture Materials

Substance	Outstanding Questions/Concerns
Vitamins (animals)	Are there different requirements for closed systems vs. net pens? Need discussion on how the differences might affect usage.
Trace Minerals (animals)	Characterization (or list) of the types of minerals to be used.
Chlorine (animals)	Culture water issues not clear. Need to change annotation to include culture water. Specific questions for a limited scope TR or expert opinion to address the purposes and use of chlorine for culture water. Category 1, Question 6: need discussion of the impact of chlorine on culture water.
Chlorine (crops)	Similar as for aquatic animals. Need more robust and detailed checklist. Need discussion of culture water.
Tocopherols (animals)	Question regarding feed manufacturing using tocopherols. Cold water vs. warm water vitamins. Is there a difference? What is the availability of tocopherols made without synthetic solvents (e.g., rosemary oil) for animal feeds?
Micronutrients (crops)	Need a discussion on multi-tropic systems and their impact on the need for routine application of micronutrients. Compare and contrast hydroponics vs. aquaculture plants – clarification needed.
Vaccines (animals)	How does stocking density affect the need for vaccines? Is there a competitive advantage if vaccinated animals escape into the ocean? Need specificity on vaccination techniques. Need discussion on management techniques that would reduce the need for vaccinations.
Lignin Sulfonate (crops)	Essentiality as it relates to the need for Lignin Sulfonate to be used as synthetic micronutrient.
Vitamins B1, B12, H	Discuss types of systems where these are now used.

Carbon Dioxide	Comment that CO_2 might only be needed at the very early stages in aquaculture system set up. Clarify. Need more information on specific uses in AQ system. Suggestion that a stronger annotation is needed to address closed tanks and possible release of CO_2 into the environment. Need update on the use of CO_2 internationally. What are alternatives for pH adjustment?

As of October 2014, all materials are currently tabled within the Livestock Subcommittee with the intention to reevaluate all materials as soon as a proposed rule for organic aquaculture standards is available. What do those standards even look like today in 2015? When will the NOP push those standards (voted on and approved at NOSB meetings in 2008 and 2009) through the federal regulatory pipeline? What is their status in that pipeline? Or will the NOP, once again, as they've done with hydroponics and nanotechnology, grossly disrespect the work of the NOSB and organic stakeholders who have taken part in the process, by ignoring their recommendations and adopting a more industry-friendly approach?

2017 SUNSET MATERIALS

Disinfectants/Antiseptics/Teat Dips:

Iodine – 2017 Sunset

SUMMARY

The Cornucopia Institute **supports the relisting of iodine** under §205.603(a) and (b) as a disinfectant, sanitizer, and medical treatment, as well as for use as a topical treatment (i.e., teat dip for milk-producing animals).

Although the option for the NOSB to add annotations was unilaterally removed by the NOP, at sunset, we believe this is an example of where it is important to add an annotation to **prohibit** the use of nonylphenol ethoxylates (NPE) forms of iodophors in organic production; NPEs are suspected endocrine disruptors and proven aquatic toxins. NPEs were banned in Europe ten years ago (in all products) and China has banned dairy product imports with NPE residues above 10 ppb.[455] There are many commercially available non-NPE iodine-based disinfectants and teat dips that can be utilized instead.

[455] Queck-Matzie, Terri. (2015). Say Goodbye to NPEs in Teat Dip. *Progressive Dairy*. January 9, 2015.

Rationale:

- Iodine is an effective antimicrobial disinfectant that kills a broad spectrum of pathogens that are both dangerous to the animals and humans that consume their meat and milk. It has a long history of use.
- Iodine products are used for a wide variety of applications in livestock production, including treating surface wounds, dipping umbilical cords, cleaning water dishes to prevent the spread of infectious diseases, cleaning equipment, and as a teat dip for milking animals.
- For food safety reasons, the teats of dairy livestock must be properly sanitized. Simple warm water and soap or homemade concoctions do not meet the requirements of the FDA's Grade A pasteurized milk ordinance nor should be used in raw milk operations where a much lower pathogen tolerance is allowed. An approved teat sanitizer must be part of the regular milking practice and iodine is one of the most effective.
- However, the inclusion of NPEs as a purported "inert" material in iodophor solutions (it helps bind the iodine and keep it in suspension) is problematic due to its toxicity. Non-NPE iodine solutions are commercially available.

DISCUSSION

Iodine is effective as a disinfecting antimicrobial due to its oxidizing effect. Iodine quickly penetrates the cell wall of microorganisms and disrupts the structure and synthesis of proteins and nucleic acids. Iodine is usually mixed with water-soluble detergents or surfactants (like NPEs) and the resulting solution is referred to as an "iodophor." Iodine-based teat dips often contain as well emollients such as glycerin or lanolin to keep the teat skin smooth and healthy.

Efficacy

As a teat dip, iodophors can be used both as a pre-milking and post-milking antimicrobial. They have shown killing efficacy against a broad spectrum of mastitis-causing bacteria, as well as fungi, viruses, and bacterial spores, including common mastitis-causing pathogens such as *S. aureus, S. agalactiae, C. bovis, and Streptococci.* However, they are not very effective as a pre-milking teat dip if there is a large amount of organic matter (mud, manure, etc.) on the teats.

An overdependence on iodine substances (or any single antimicrobial substance) could potentially lead to a growing number of pathogens displaying resistance to a given antimicrobial. According to the 2015 Iodine TR, it has been concluded that the "scientific evidence does not support a widespread emerging resistance among mastitis pathogens to antimicrobial drugs."[456] However, researchers caution that resistance of pathogens such as *Staph aureus* (the most prevalent mastitis-causing pathogen worldwide) to chemical disinfectants may develop if these compounds are used at

[456] Pritchard 2006: http://www.cals.ncsu.edu/an_sci/extension/dairy/newsletters/0306nlet.pdf

concentrations below those required for optimal effectiveness.[457] Because of this concern, only established effective concentrations of germicide compounds should be used as teat dips. If sublethal doses of germicides are used whereby only a percentage of the pathogens are killed, the pathogens that survive rapidly multiply replacing those that were killed off. Exposure to sublethal doses of antibiotics/germicides creates selective pressure conditions, which favor resistance development in pathogens over time.

There are advantages and disadvantages to each synthetic teat dip approved for use in organic production, which are summarized in table 1 below.

Table 8: Comparison of NOP-approved Synthetic Teat Dips (Including Petitioned ASC)

	Description*	Advantages	Disadvantages
Iodine (including concentrations of 0.05% to 1.0%)	-Broad spectrum germicide effective against all mastitis-causing bacteria, as well as fungi, viruses, and bacterial spores	-Readily available with many commercial formulations -Most tested germicide in the industry	-Sublethal use can create resistance issues -Not effective when teats are dirty -Can impart residues in the milk -NPEs are toxic to aquatic life and potential endocrine disruptors -Earthquake in Japan limited production (only produced in a few places) -Can be irritating to skin; requires emollients such as lanolin or glycerin
Chlorhexidine (including compounds: digluconate, gluconate, diacetate)	-Rapidly acting, nonirritating germicide effective against most Gram-positive and -negative bacteria, as well as some viruses	-Non-irritating to the skin -Kills bacteria for an extended period of time -Shows more efficacy on Staph aureus than iodine	-Can be expensive -Can only be used under veterinary supervision according to NOP listing -More toxic to manufacture than iodine
Hydrogen Peroxide	-Broad spectrum germicide effective against most mastitis-causing bacteria. Even more effective if combined with lactic acid.	-Affordable	-Less research on this germicide than the others -Shorter shelf life, sensitive to sunlight
Alcohols (Ethanol & Isopropanol)	Usually used in combination with other substances, such as iodine. Often used in wipes, which is not the same as a teat	-Affordable and readily available -Relatively benign substances	-Ineffective against bacterial spores[458] -Will dry out teats -Isopropanol is not approved

---

[457] Behiry AE, Schlenker G, Szabo I, Roesler U. 2012. *In vitro* susceptibility of *Staphylococcus aureus* strains isolated from cows with subclinical mastitis to different antimicrobial agents. Journal of Veterinary Science 13(2): 153–161; doi:10.4142/jvs.2012.13.2.153.

[458] CDC 2008

	dip.		for topical use
Proposed: Acidified sodium chlorite (containing lactic or mandelic acid)	Broad spectrum germicide effective against Gram-positive and -negative bacteria, as well as molds, yeasts, and viruses	-Kills the widest range of bacteria in the face of high organic load (dirty teats) -Leaves no residues according to petitioner -Quick kill in as little as 15 seconds -Gentler on the teats	-Has to be mixed on site -Occupational health risks of chlorine dioxide inhalation -Limited research as a teat dip -Is a chlorinated substance, the manufacturing of which has many negative environmental consequences
* From "Choosing the Best Teat Dip for Mastitis Control and Milk Quality" by Stephen Nickerson From the National Mastitis Council's Summary of Peer-Reviewed Publications on Efficacy of Premilking and Postmilking Teat Disinfectants Published since 1980 (2009 revision)			

Pre-milking iodine teat dips should be completely wiped off before milking to minimize residual transfer from the teat to the milk.[459] Although most humans exhibit iodine deficiency some individuals are intolerant to high levels of iodine and develop thyroid problems as a result, so excess levels of iodine in milk should be prevented. Furthermore, the NPE compounds that are in many iodophor solutions have been shown to be endocrine-disruptors[460], another reason why extreme care should be taken not to leave any iodophor teat dip residues on the skin or inside the teat.

CONCLUSION

The Cornucopia Institute **supports the relisting of iodine on §205.603(a) and (b)** but with an annotation prohibiting NPE inerts in the formulation. Iodine is an effective, readily available antimicrobial with a wide range of uses and is an effective teat dip for the control of pathogens that may harm dairy animals as well as be transferred into the milk.

Parasiticides/Anthelmintics – 2017 Sunset

Table 9: Comparison of NOP-approved Synthetic Parasiticides

Parasiticide	Ivermectin	Moxidectin	Fenbendazole
Properties	• Chemical class: Macrocyclic Lactone • Use on: Cattle, sheep,	• Chemical class: Macrocyclic Lactone • Use on: Cattle, sheep,	• Chemical class: Benzimidazoles • Use on: Cattle,

459 Borucki-Castro, S.I., R. Berthiaume, A. Robichaud, P. Lacasse. (2012). Effects of iodine intake and teat-dipping practices on milk iodine concentrations in dairy cows. *Journal of Dairy Science*. 95(1): 213-20.
460 US EPA. (2010). Nonylphenol (NP) and Nonylphenol Ethoxylates (NPEs) Action Plan. US Environmental Protection Agency, August 2010. Retrieved Feb 19, 2015 from: http://www.epa.gov/oppt/existingchemicals/pubs/actionplans/RIN2070-ZA09_NP-NPEs Action Plan_Final_2010-08-09.pdf

	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	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	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[461]. 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[462] • Can be toxic to certain soil invertebrate species, but at levels that are environmentally unrealistic[463] • Certain parasites can build resistance. There are methods to slow resistance build-up, but none to stop it[464], [465]	• 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[466] • Just like Ivermectin, has 'non-target effects' on dung breeding insects and manure degradation[467] • Highly toxic to zebrafish[468] • Also like Ivermectin, certain parasite species can build resistance to Fenbendazole[469]

461 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.

462 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.

463 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.

464 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.

465 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).

466 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.

467 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.

	• 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 – 2017 Sunset

SUMMARY

The Cornucopia Institute is **neutral on the relisting of ivermectin** at §205.603 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" products 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. Synthetic parasiticides must not be administered on a routine basis.*

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

---

[468] 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.
[469] 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.

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."

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. The restrictive annotation in the listing should prevent the overuse of this material.

Unfortunately, the most current TAP is from 1999. A new TR is not yet available to the public. This is totally unacceptable as it impedes efforts by citizens and organizations to make informed summary reviews of the important, and potentially controversial, substances of this nature. There is a considerable amount of new scientific information on ivermectin that has been published since 1999.

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**.[470] 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.[471]

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.[472] **If livestock manure breaks down more slowly, not only can it harbor more parasites and fly**

---

[470] Wall, R. and L. Strong. (1987). Environmental Consequences of Treating Cattle with the Antiparasitic Drug Ivermectin. *Nature* 327: 418-421.

[471] Madsen, M. (1990). Treating cattle with Ivermectin: Effects on the Fauna and decomposition of dung pats. *Journal of Applied Ecology*. 27: 1-15.

[472] 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.

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 animals' milk. For this reason, ivermectin is not approved for use on dairy animals (but topical moxidectin, another macrocyclic lactone, is).[473]

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.[474],[475] Jackson-O'Brien's research showed that a pumpkin seed

---

[473] 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.

[474] 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.

[475] 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

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).

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.[476] 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.[477] Also, a very infected, wormy animal will often be condemned by USDA inspectors at slaughter, so there is an additional economic loss from parasitism.

---

[476] Waldridge, B.M. (1998). Weight Loss and lethargy: diagnostic challenge. *Veterinary Forum* (May): 72-73.
[477] Luginbuhl J. M. (1997). Roundworms in goat herds. Livestock Newsletter. http://jackson.ces.stat.nc.us/newsletters/livestock/jan-feb97

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.

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.

CONCLUSION

The Cornucopia Institute is **neutral on the relisting of ivermectin** on §205.603 as a restricted parasiticide.

Moxidectin – 2017 Sunset

SUMMARY

The Cornucopia Institute is **neutral on 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 above. 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) (Moxidectin TAP Report 2003).

The most current TAP is from 2003. A new TR is not yet available to the public. This is totally unacceptable as it impedes efforts by citizens and organizations to make informed 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 1-42 days previously with MOX in an injectable or topical formulation had no effect on reproductive success.[478] 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, and thus it is not likely to contaminate water sources nor 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 and those residues tended to concentrate in the curd and ripening sheep

---

[478] 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.

cheese.[479] 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 above, 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 poignant 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.

CONCLUSION

The Cornucopia Institute is **neutral on the relisting of moxidectin on §205.603** as a restricted parasiticide.

Fenbendazole – 2017 Sunset

SUMMARY

The Cornucopia Institute is **neutral on 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*

[479] 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.

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 <u>action similar or identical to synthetic chemical pesticides and/or antibiotics</u>. For example, fenbendazole is closely related to the fungicides benomyl and thiabendazole.

The current TAP is from 1999. A new TR is not yet available to the public. This is totally unacceptable as it impedes efforts by citizens and organizations to make informed summary reviews of the substance. There is a considerable amount of new scientific information on fenbenzadole that has been published since 1999.

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 natural 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.[480] As noted in the table above, there is evidence that this parasiticide is toxic to zebrafish, so high levels of excretions like this are definitely a concern.

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.[481]

---

[480] Adams, H.R. (1995). Veterinary Pharmaceuticals and Therapeutics, 7th edition. Ames: Iowa State University Press.

[481] 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.

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, regular fecal examination, culling heavily infected animals, selection of resistant breeds and breeding stock, and 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.[482],[483]

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.[484]

CONCLUSION

The Cornucopia Institute is **neutral on the relisting of fenbendazole on §205.603** as a restricted parasiticide.

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

---

[482] 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.

[483] 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

[484] 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.

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 ivermection, in 2006, it failed to get the two-thirds majority to pass (Yes: 6, No: 4, Abstain: 2, Absent: 2), yet it still, somewhat mysteriously, 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.

Without a new and thorough Technical Review for each substance, it is difficult to confidently say whether or not all three materials are needed or not. They each have their efficacies, advantages, and disadvantages. Additionally, the problem of anthelmintic resistance is a serious and growing problem. Yet how is the use of parasiticides, even as a last resort, any different than the use of antibiotics? If antibiotics are prohibited in organics, then maybe broad-spectrum parasiticides should be prohibited as well. For those reasons, and the fact that new Technical Reviews are not available to thoroughly research these substances, The Cornucopia Institute **remains neutral on the relisting of them**.

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*** 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.
- 90-day withholding periods seem excessive and shorter withholding periods are supported by research.

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 actually approved for cattle by the FDA,[485] lidocaine has become the mostly commonly used local anesthetic in veterinary medicine in the U.S.[486] It is also considered the most effective, as it is short acting and longer lasting than other commonly available local anesthetics such as procaine.[487]

Lidocaine hydrochloride is a water-soluble injectable drug which acts quickly to numb an injection site to reduce the feeling of pain. It is regularly used for reducing pain during surgery or dehorning, or for treating painful wounds, or as an epidural. While the local synthetic anesthetic procaine can also be used, its action is slower to take effect and it 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 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, as it is used as an injectable local anesthetic during surgery or dental procedures, and used 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

---

[485] 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

[486] https://instruction.cvhs.okstate.edu/.../pdf/14LocalAnesthesia2006b.pdf

[487] 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

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. It's questionable as to whether such a long withholding period is necessary for meat animals. 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 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.[488]

Research in dogs, cats, sheep, horses, and rats demonstrates rapid elimination of lidocaine and its metabolites, usually within several days of administration.[489] Research available from cattle suggests that half-lives of drugs are typically shorter in cattle than in dogs and cats or humans.[490] 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 four days for meat and 72 hours for dairy.[491]

---

[488] 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

[489] Ibid.

[490] Baggott JD. The Physiological Basis of Veterinary Clinical Pharmacology. Oxford: Blackwell, 2001

[491] 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.

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.

CONCLUSION

Lidocaine is a widely used, readily available, relatively safe local anesthetic with no better alternatives. The Cornucopia Institute supports relisting of this important drug. Additionally, Cornucopia supports shortening the withholding period for meat to a time period more in line with what the research shows to be reasonable to reduce the risk of any hazards to human health.

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**. Unfortunately, a new Technical Report was not available to properly review this substance at the time of this writing. The 2010 TAP review is incomplete and lacks scientific rigor**.

Rationale:

- Chlorhexidine is a rapidly acting, non-irritating germicide composed of biguanide compounds.
- Questions still remain as to the manufacture of this material, its potential impact on the environment and human health, and whether any occupational hazards or animal impacts could result from its regular use. All of this information may be contained in the new Technical Report, not yet available to the public (a disservice to organic stakeholders and to NOSB members who might benefit from their informed comments).

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.[492] It 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.

Its disadvantages are that it is more toxic to produce (according to the brief 2010 TAP) than many of the other approved antimicrobials, it can be expensive to purchase, and it requires veterinary supervision. See table 1 in the above Iodine section to compare the pros and cons of different synthetic teat dips.

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.[493] 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.

CONCLUSION

The Cornucopia Institute **supports the relisting of chlorhexidine on §205.603(a)** but only if its restricted-use status remains intact. A new Technical Report was not yet available to properly review this substance, thus many questions remain as to its manufacturing, human health impacts, and potential resistance-development issues.

---

[492] Nickerson, Stephen C. (2001). Choosing the Best Teat Dip for Mastitis Control and Milk Quality. *NMC-PDPW Milk Quality Conference* Proceedings. April, 2001.
[493] 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.*

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.[494]

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.[495] Hydrogen peroxide is a known mutagen and is exhibits genotoxicity in mammalian and human cell lines.[496], [497] The International Agency for Research on

---

[494] US EPA. (2007). Peroxy Compounds: Hydrogen Peroxide and Peroxyacetic Acid Environmental Fate Science Chapter. US Environmental Protection Agency.
[495] ATSDR. (2014). Medical Management Guidelines for Hydrogen Peroxide. Agency for Toxic Substances & Disease Registry.
[496] IARC. (1999). IARC Monographs on the Evaluation of Carcinogenic Risks to Humans: Hydrogen Peroxide. International Agency for Research on Cancer.

Cancer (IARC) determined 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.*[498]

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.[499]

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 on the teat physically helps to clean them, making it an excellent pre-dip.[500] 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.

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.

---

[497] 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.

[498] IARC. (2014). Agents Classified by the IARC Monographs, Volumes 1–111. International Agency for Research on Cancer.

[499] US EPA. (2007). Peroxy Compounds: Hydrogen Peroxide and Peroxyacetic Acid Environmental Fate Science Chapter. US Environmental Protection Agency.

[500] Belsito, Jessica. (2012). Alternative teat dips: Weighing cost and quality. *Progressive Dairyman*. March 16, 2012.

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 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.[501],[502] 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.[503] 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.[504]

Human health concerns

---

[501] 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.

[502] 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.

[503] 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.

[504] McDonnell G, Russell AD. (1999). Antiseptics and disinfectants: activity, action, and resistance. *Clinical Microbiology Reviews* 12:147–179.

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.[505]

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.[506] Considering the continued advancements in fermentation-based technologies and increasing global demands for fuel ethanol, this figure was closer to 95% in 2013.[507]

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.[508] 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%-90% 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

---

[505] US EPA. 1995. Reregistration Eligibility Decision (RED): Aliphatic Alcohols. US Environmental Protection Agency.
[506] Logsdon JE. 2004. Ethanol. Kirk-Othmer Encyclopedia of Chemical Technology
[507] Berg C. (2013). World Fuel Ethanol: Analysis and Outlook. Prepared for the Japanese Ministry of Economy, Trade and Industry (METI).
[508] Papa AJ. 2011. Propanols. Ullman's Encyclopedia of Industrial Chemistry.

matter. Alcohols are highly flammable, can cause damage to rubber and plastic, and can be very irritating to injured skin.[509]

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.[510]

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[511] 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).

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, unilaterally implemented, NOP sunset procedures) 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 alternative materials such as ethanol, hydrogen peroxide, iodophors, etc., as a replacement.

---

[509] 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.
[510] McDonnell G, Russell AD. (1999). Antiseptics and disinfectants: activity, action, and resistance. *Clinical Microbiology Reviews* 12: 147–179.
[511] CDC 2008

NANOTECHNOLOGY

Experts on nanotechnology are virtually unanimous that nano-scale materials have the potential for structure-dependent health effects that are uniquely different than their larger counterparts.[512,513,514]

In the fall of 2010, the NOSB adopted a policy that defined "engineered nanomaterials" and recommended that the NOP prohibit them in organic products and take steps to avoid their accidental or incidental presence.

The NOSB defined "engineered nanomaterials" as follows:

> *Engineered nanomaterials: substances <u>deliberately</u> designed, engineered and produced by human activity to be in the nanoscale range (approx 1-300 nm) because of very specific properties or compositions (e.g,. shape, surface properties, or chemistry) that result only in that nanoscale. Incidental particles in the nanoscale range created during traditional food processing such as homogenization, milling, churning, and freezing, and naturally occurring particles in the nanoscale range are not intended to be included in this definition. All nanomaterials (without exception) containing capping reagents or other synthetic components are intended to be included in this definition. [emphasis added]*

The NOSB requested that "the NOP work with the NOSB on the adequacy of the definition, any potential areas of concern that may not be included in this definition, parts of this definition that are not workable within enforcement, and possible adjustments to the approximate size constraints that may be needed."

Instead, the NOP unilaterally responded with the following statement:

> *To avoid conflicts about the presence of nanomaterials in substances regulated by other Federal agencies, the NOP is **not** establishing a separate definition for engineered nanomaterials, such as the definition recommended by the NOSB. The descriptions in the U.S. **Food and Drug Administration**'s Guidance for Industry Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology and the U.S. **Environmental Protection Agency**'s policies on Regulating Pesticides that Use Nanotechnology and Control of Nanoscale Materials Under the Toxic Substances Control Act should be used as applicable. [emphasis added]*

---

512 Buzea, C.; Pacheco, I. I.; Robbie, K. (2007). "Nanomaterials and nanoparticles: Sources and toxicity". *Biointerphases* **2** (4): MR17–MR71.
513 Jonaitis, TS; Card, JW; Magnuson, B (2010). "Concerns regarding nano-sized titanium dioxide dermal penetration and toxicity study". *Toxicology letters* **192** (2): 268–9.
514 Paull, J. & Lyons, K. (2008). "Nanotechnology: The Next Challenge for Organics". *Journal of Organic Systems* **3**: 3–22.

In fact, **the EPA and FDA do not agree on a definition.** The two EPA documents cited state that nanomaterials are in the size range of approximately 1-100 nm. On the other hand, the FDA document is more consistent with the NOSB recommendation, considering also "[w]hether a material or end product is engineered to exhibit properties or phenomena, including physical or chemical properties or biological effects, that are attributable to its dimension(s), even if these dimensions fall outside the nanoscale range, up to one micrometer (1,000 nm)."

The NOP further clarified that the EPA definition would be used when looking at pesticides and the FDA definition would be used when looking at food additives.

It should be noted that, historically, the NOSB and NOP have adopted rulemaking that radically differs from that of other federal regulatory agencies. Consumers who turn to organic food because they do not trust regulators to assure the safety of conventional food have a long legacy of reasons for doing so.

One of the reasons Congress created the National Organic Standards Board was so it could serve as a buffer insulating organic rulemaking from the same type of political and economic influence of the agribusiness and biotechnology industries wheeled in Washington.

Sadly, this is just the latest chapter in the USDA's National Organic Program violating the will of Congress, by their gross disrespect for the expert, volunteer-members of the NOSB, and organic stakeholders, who spend thousands of dollars, and untold hours, in the collaborative process that develops NOSB resolutions/recommendations.

The NOP policy takes a neutral stance towards nanotechnology stating: **"The NOP does not consider nanotechnology to be intrinsically benign or harmful." In contrast,** the NOSB's policy prohibited all use of "engineered nanotechnology" in organics **stating: "**There is overwhelming agreement within the organic industry to prohibit nanotechnology **in organic production and processing at this time." [emphasis added]**

The NOSB policy requested that the NOP "accept the definition [they adopted] as synthetic substances, that they may have unique properties that distinguish them from all listings of these substances in a bulk form, and that **they are not allowed by a listing of the bulk form of the substance on the NL, or otherwise allowed in organic production**, <u>pending a further recommendation from the NOSB</u>, and implementation thereof by the NOP, on the use, or prohibition, of engineered nanomaterials in organic production processing and packaging." [emphasis added]

The NOSB recommendation could have been codified in the regulations by adding the NOSB definition at §205.2 and the prohibition at §205.105, Allowed and prohibited substances, methods, and ingredients in organic production and handling, by adding (h) engineered nanomaterials.

In contrast, the NOP invites petitions for nanomaterials:

> *As with other substances, no engineered nanomaterial will be allowed for use in organic production and handling* ***unless*** *the substance has been: 1) petitioned for use; 2) reviewed and recommended by the NOSB; and 3) added to the National List through notice and comment rulemaking.*

The NOSB also expressed concerns about contamination of organic products from packaging, food contact surfaces, and water sources. The NOP has failed to address these concerns.

CONCLUSION

We urge the NOSB to make a strong statement protesting the nanotechnology policy memo issued by the National Organic Program.

The NOP must act to protect organic products and production. Its mission is not necessarily in alignment with that of other agencies, and the NOP must not depend on other agencies with less protective purposes to take the lead in preventing the intrusion of unwanted technology into organic products and production.

The NOP Policy Memo 15-2 exhibits gross disrespect in the "NOSB process" and is at odds with the policy passed by the deliberative body. The unilateral position the NOP has made public allow materials to be listed on the National List that would not be allowed according to the policy adopted by the NOSB.