











# Comments to the National Organic Standards Board

October 28–30, 2014 Meeting Louisville, Kentucky



# The Cornucopia Institute's

# Comments to the

# **National Organic Standards Board**

Fall 2014 Meeting October 28–30 Louisville, Kentucky

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# **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.

# **MATERIALS SUBCOMMITTEE**

# **Research Priorities Proposal for 2014**

The Cornucopia Institute supports many of the research priorities recommended by the Materials Subcommittee. These include some of the research topics identified in 2012: whole farm systems, alternatives to antibiotics, and methionine alternatives.

In addition, we support some of the new priorities proposed including **herd health**, **pastured poultry and salmonella, and reduction of genetically modified content of breeding lines**.

The Cornucopia Institute **also recommends** the following research priorities for consideration:

- The remediation of persistent herbicides that commonly carry over in compost, especially aminopyralids and other pyridine carboxylic acids.
- Testing for biodegradable bioplastic mulch products and their effects on soil biology, crop health, and uptake by plants.
- Alternative mulching materials.
- Plant-based medicinals for controlling animal infections (especially respiratory infections).
- Sulfurous acid's efficacy in reclaiming alkaline soils and irrigation water; human health and safety issues; sulfur dioxide emissions from sulfur burners.
- Moving mechanical delinting processes from the research phase to commercial availability.

The Cornucopia Institute does <u>not</u> recommend that the following research topics, while worthy of attention, be listed as <u>high</u> priority, as recommended by the Materials Subcommittee:

- 1. The fate of genetically engineered plant material in compost
- 2. Possibilities for organic aquaculture
- 3. Aquatic biodiversity
- 4. Commercial availability assessments
- 5. Consumer demand

# <u>Discussion Document: Excluded Methods</u> <u>Terminology</u>

### **SUMMARY**

The definition of "excluded methods" in the USDA Organic Regulations (7 CFR 205.2; Terms Defined) is:

A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology). Such methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture.<sup>1</sup>

Since this definition was developed in 1995, several issues have come to require further clarification. These include:

- Genetically engineered vaccines for livestock
- The use of GMOs used to make biodegradable bioplastic mulches
- The use of genetically mutated algae
- Untraceable plant breeding techniques such as double haploid production, irradiation, cell fusion, and embryo rescue

The first discussion document (2013) further defined and discussed terms, and suggested that more work was needed to clarify what terms were and were not excluded methods. The second discussion document (August 2014) summarized the public comments received on the first discussion document and posed further questions to clarify Excluded Methods Terminology for accredited certifiers and organic producers.

### DISCUSSION

### Process vs. Product

We agree with the Materials/GMO Subcommittee recommendation to keep the "U.S. organic regulations a process-based system," and that "it would make sense that this

<sup>&</sup>lt;sup>1</sup> Federal Register, Vol. 65, No. 246, 12/21/2000, Rules and Regulations p. 80639

concept carry over to defining excluded methods."

The Senate report that accompanied OFPA, which was quoted in the first proposed rule (62 Fed. Reg. 65850, 65875), states that:

... as time goes on, various scientific breakthroughs, including biotechnology techniques, will require scrutiny for their application to organic production. The committee is concerned that production materials keep pace with our evolving knowledge of production systems.<sup>2</sup>

Currently, consumers expect genetic engineering (other than traditional plant breeding methodology) to be absent throughout the entire process of organic agriculture. While there is flexibility in the current rule to evolve in the future, current consumer expectation does not want genetic engineering in the *process* even if GMOs are absent from the final *product*.

### Discrepancies between the law and reality

Genetic manipulation of plant breeding materials has already occurred in many crop varieties that are currently widely used in organic farming.

These techniques include:

- Embryo rescue to introduce resistance genes
- Colchicine gene doubling
- Double haploid production to get homozygosity in one generation
- Mutations through irradiation and exposure to harsh chemicals (classic mutagenesis)
- Cell fusion within plant families to create male sterility in brassica hybrids

Some of these techniques are no longer traceable since they were used in initial crosses and have been passed down through many generations. Many of these techniques are standard in the majority of public and private plant breeding labs. Likewise, there are many new varieties in development that are using these techniques for issues relevant to organic agriculture including resistance to diseases, insects, drought, salinity, and reduced soil fertility.

The NOP will have to clearly address this discrepancy. If the techniques listed above are excluded, seeds developed prior to this ruling may need to be "grandfathered in" and a new system for tracking a seed's genetic history in terms of organic excluded techniques needs to be put into place and made known in seed catalogs.

<sup>&</sup>lt;sup>2</sup> U.S. Senate. 1990. Food, Agriculture, Conservation and Trade Act of 1990. Report to Accompany S2830. Rpt 101-357, 101st Congress, 2nd Session. Government Printing Office, Washington, DC.

Similar to our discussions of Seed Purity, the discrepancies between what is expected in organic agriculture and the reality of what occurs must be addressed. In other words, because of pollination, genes from genetic engineering will be detected in organic products. Likewise, it will be ultimately challenging, if not impossible in many cases, to exclude genetic material created from techniques that have been used in breeding facilities for decades.

### A need to clarify what is and isn't allowed

Applying European Classification Concepts to the NOP to try to distinguish between traditional and transgenic breeding techniques for both plants and animals is needed for clarification.

The Research Institute of Organic Agriculture (FiBL) has a chart that could be developed over time for the NOP that could begin with the Cartagena Protocol definitions and proceed from there. The chart would define the technique, whether or not it is excluded, and why. The end goal is the ability to certify "organic **varieties**" and "organic animal **breeds**." A chart such as this maintains transparency to all stakeholders and gives accredited certifiers clear instruction on how to evaluate seeds, vaccines, microorganisms, and other potential GMOs.

While identifying/approving organic varieties is necessary, The Cornucopia Institute is concerned about the sudden impact on growers should many seed varieties quickly be excluded. Varieties currently available to organic producers need to be thoroughly assessed before any prohibitions on their availability can be implemented.

### **CONCLUSION**

The Cornucopia Institute recommends that:

- Regulations for excluded terminology should be process-based (rather than product-based) to be consistent with current organic rule.
- Discrepancies between techniques that are not allowed (such as cell fusion) and the realities of the techniques used throughout the history of crop breeding should be addressed.
- A European Classification Concept should be applied to the NOP for excluded techniques for public transparency and clarification for certifiers.

# HANDLING SUBCOMMITTEE

# **Glycerin**

### **SUMMARY**

**Support** the petition to remove glycerin as an allowed synthetic material for handling at §205.605(b) of the National List.

### Rationale:

- As per the petition, certified organic glycerin can now be produced in sufficient quantities utilizing only the "mechanical and biological processes" required in §205.270.
- ➤ The transition from synthetic glycerin to organic glycerin is an example of organic regulations pushing industry toward safer and more organic-compliant practices. Removing synthetic glycerin from the National List (i.e., glycerin produced by hydrolysis of fats and oils) will encourage additional glycerin production consistent with organic principles.

### **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.<sup>3</sup> The synthetic glycerin that is currently used in organic handling is produced by the application of steam or permitted synthetic alkalis such as sodium hydroxide, sodium carbonate, and potassium hydroxide.<sup>4</sup>

### Synthetic glycerin is not essential

The petition will cause an allowed synthetic to be replaced by something that is truly organic. A large number of producers currently manufacture organic glycerin at purportedly competitive prices, thus making the listing of synthetic glycerin unnecessary.<sup>5</sup>

<sup>&</sup>lt;sup>3</sup> Draco Natural Products. 2013. Petition to remove glycerin from the National List.

<sup>4</sup> Ibid.

<sup>&</sup>lt;sup>5</sup> USDA AMS Agricultural Analytics. 2013. Glycerin Technical Evaluation Report.

There are many sources of certified organic glycerin. Table 5 (line 673) of the TR includes 21 certified organic operations that manufacture or source organic glycerin. The TR appears to be incomplete as the Organic Trade Association's directory of organic producers lists four additional companies.<sup>6</sup> They are Daabon Organics USA, Inc., Earth Supplied Products, LLC, Materia Organica, and Jedwards International, Inc. A web search produced even more sources.<sup>7</sup>

While there may not have been organic alternatives to synthetic glycerin when it was originally added to the National List, clearly that is no longer the case. Synthetic glycerin is no longer essential given the wide availability of organic glycerin in the marketplace.

### No incentive for processors to use non-synthetic glycerin

Glycerin produced by fermentation of organic corn, as opposed to synthetic glycerin, is available to organic processors in sufficient quantities. Removing glycerin from the National List of allowed synthetics will incentivize the market resulting in the use of organically produced glycerin consistent with §205.270, which requires mechanical or biological methods of production.

### 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 List will move processors towards using organic glycerin, which is now commercially available. The organic handling industry is expected to adjust as organic sources for materials become available. **The Cornucopia Institute supports the majority opinion on the Handling Subcommittee to remove glycerin from the National List**.

<sup>&</sup>lt;sup>6</sup>http://www.theorganicpages.com/topo/commercialactivity.html?ca=ingredients&commid=36&keyw=1 726. Viewed September 9, 2013.

<sup>&</sup>lt;sup>7</sup> From Nature with Love (<a href="https://www.fromnaturewithlove.com">https://www.fromnaturewithlove.com</a>), Essential Wholesale and Labs (<a href="http://www.essentialwholesale.com/">http://www.essentialwholesale.com/</a>), Allyson Enterprises, Inc. (<a href="http://www.allysonenterprises.com/">http://www.allysonenterprises.com/</a>)

# **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 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.
- ➤ It is 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 that are organic. These include milk, cream, eggs, butter, starches, and gums.
- ➤ The Handling Subcommittee voted to reject the petition, mainly due to lack of information from CBI. 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.

### Unknown 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.

### Organic 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**

The Handling Subcommittee did its due diligence in evaluating this product, but was unable to get the answers they needed to fully research this material. Due to the inaccessibility of product information classified as "Confidential Business Information," the unknown health impacts, and the fact that organically produced alternatives exist, the petition to list Whole Algal Flour on the National List under §205.606 should be rejected.

# **Ancillary Substances**

At its April 2013 meeting, the NOSB adopted a recommendation to review ancillary substances found in food handling substances. The NOSB recommended that a review be conducted according to OFPA as generic substances come up for sunset review or as new substances are petitioned. The review would not require the ancillary substances to be individually listed on the National List. The NOP could indicate restrictions or prohibitions in annotations for the generic substances or in published guidance regarding permitted substances for organic handling.

In February 2014, the NOP sent a memorandum to the National Organic Standards Board regarding a Trial Process for Ancillary Substance Review with the 2016 sunset material microorganisms under the following procedure:

- 1. The NOSB Handling Subcommittee determines whether ancillary substances are present in a substance under sunset review. Information to aid in this determination may be available as part of a technical report or through public comment.
- 2. If ancillary substances are not present:
  - a. The NOSB Handling Subcommittee indicates this in its preliminary sunset review which is posted for public comment prior to the next public meeting.
  - b. The NOSB uses this preliminary sunset review to inform its full sunset review at the next public meeting. The NOSB's findings are documented as part of its final NOSB sunset review.
- 3. If ancillary substances are present:
  - a. The NOSB Handling Subcommittee evaluates whether the ancillary substances should be allowed in organic handling using the OFPA criteria (7 USC 6518(m)).
  - b. The NOSB Handling Subcommittee develops a separate ancillary substance proposal distinct from its sunset review to indicate whether the ancillaries should be allowed or restricted.
  - c. The NOSB Handling Subcommittee makes any proposal on ancillary substances available for public comment prior to the next public meeting.
  - d. The NOSB makes a recommendation on any proposals at the next public meeting.

e. The NOSB submits its recommendation to NOP for any future guidance, policy memos or rulemaking as necessary.

The Cornucopia Institute urges that ancillary substances are thoroughly reviewed. There is no legal basis that indicates these materials should be exempted from the full reviews required in OFPA. It is crucial that ancillary substances are thoroughly examined in the Technical Reports completed for new petitions and sunset materials.

Finally, a material should not be approved for addition to the National List if an ancillary substance is present in the final product and the review of this ancillary substance fails OFPA's criteria including health and environmental impacts, essentiality, and compatibility with organic practices.

# **Sunset Materials - 2015**

Note: The Cornucopia Institute submitted comments on these 2015 Sunset Materials at the Spring 2014 NOSB meeting. Only new information and analysis is presented here.

### **SUMMARY**

The following sunset materials are up for discussion at the Fall 2014 NOSB meeting. The Handling Subcommittee recently voted to relist or remove the following materials:

- ➤ Gellan gum (high acyl form only): Motion to remove failed (0 yes, 6 no)
- > Tragacanth gum: Motion to remove failed (0 yes, 6 no)
- Marsala (fortified cooking wine): Motion to remove passed (6 yes, 0 no)
- Sherry (fortified cooking wine): Motion to remove passed (6 yes, 0 no)

The Cornucopia Institute agrees with the motion to remove for both Marsala and Sherry since similar ingredients are both available in organic form and there is little documentary evidence of these wines still being used by organic processors. Thus, they fail the OFPA category of essentiality.

However, we do believe that both gellan gum and tragacanth gum should be taken off the list for the following reasons:

- ➤ Technical Reports (TR) are either missing or inaccurate. Only gellan gum has a TR, which is 10 years old and only 6 pages long.
- ➤ Gellan gum is a highly processed **synthetic** material with isopropyl alcohol (a processing aid which is prohibited in organics) residues up to .075%. Although the addition of gellan gum may add "better mouthfeel" to some highly processed organic 'foods,' it is hardly an essential product. Other thickeners such as gum arabic, pectin, and agar agar can be used as alternatives.
- > Tragacanth gum is non-essential as few if any organic handlers are using this material due to its limited supply. Most organic handlers are using the more plentiful gum arabic, available in organic form, as an alternative.

### **DISCUSSION**

The Cornucopia Institute requests that new, thorough Technical Reviews be completed for both gellan gum and tragacanth gum before they are considered for relisting.

Cornucopia requests that a new TR be performed for every material that is up for sunset review. Further, we request that subcommittee discussions and proposals should be based on information in the new TR.

### **Gellan Gum - Sunset**

When originally petitioned by CP Kelco in 2004, the company asked for gellan gum to be considered a non-organic *synthetic* substance. Yet for some reason the word "synthetic" has disappeared from the current listing. **Gellan gum is a synthetic substance and should be reviewed as such**. When there are non-synthetic (natural) substances such as gum arabic, guar or locust bean gum, non-amidated pectin, or agar agar available as alternatives, why would it be appropriate keep a synthetic substance on the list?

### **Tragacanth Gum - Sunset**

Tragacanth gum is made from the dried root sap of several species of the legume *Astragalus*. Another organically available emulsifier, thickener, and stabilizer is gum arabic, which is nearly identical in performance to tragacanth gum, according to the original petitioner. Because of limited supplies, mostly due to trade sanctions, war, and other political instability in the countries of origin, most organic handlers are using organic gum arabic instead. If this material is not needed, then it fails the essentiality criteria.

### **Marsala and Sherry - Sunset**

The Cornucopia Institute contacted the original petitioners of marsala and sherry, Fairfield Farm Kitchens, and they are no longer using these cooking wines in their products.

Organic sources of marsala- and sherry-like wines (such as Organic Wine Company in San Francisco) exist to meet any demand for marsala and sherry in organic products.

Therefore, marsala and sherry should not be relisted under §205.606 because they are not essential and organic alternatives are available.

### CONCLUSION

Materials should not be relisted without up-to-date Technical Reviews. The Handling Subcommittee should request TRs for the two gums prior to considering them for relisting. Discussion of sunset materials at NOSB meetings should be postponed until after the new TRs are available for public review.

Marsala and sherry cooking wines are both available in organic form and thus should be taken off the National List. Gellan gum is synthetic and non-essential and tragacanth gum is being replaced by the more available organic gum arabic; therefore, they should no longer be on the National List.

# **Sunset Materials - 2016**

### **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

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 TRs. There are several issues with the current status of the Technical Reports:

- **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. A lot of 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.

# **Egg White Lysozyme - Sunset 2016**

Egg white lysozyme is a purified enzyme material isolated from hen egg white. The enzyme is commonly used as a preservative and 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 TR, but that determination is questionable to our scientific staff based on the use of solvents.

Egg white lysozyme was added to the National List under §205.605(a) Non-Synthetic, Non-Agricultural Substance on September 11, 2006, based on a re-assessment of egg white lysozyme by the NOSB at the May 2003 meeting. The first sunset review of egg white lysozyme took place at the November 2009 meeting.<sup>8</sup> No comments or disagreements were presented at that time.

### International regulations

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.<sup>9</sup>

### GRAS status pending

The FDA regards egg white lysozyme as Generally Recognized As Safe (GRAS), in the tentative final ruling dated March 13, 1998. 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.<sup>10</sup>

http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm153975.htm

<sup>8</sup> http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5081504

<sup>&</sup>lt;sup>9</sup> Lysozyme in Wine: An Overview of Current and Future Applications http://onlinelibrary.wilev.com/doi/10.1111/1541-4337.12102/pdf

<sup>&</sup>lt;sup>10</sup> FDA Agency Response Letter GRAS Notice No. GRN 000064.

### 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.<sup>11</sup>

The 2011 EFSA opinion reviewed the Oenological Products and Practices International Association (OENOPPIA) application to permanently exempt the egg white lysozyme from labeling requirements on wine. The panel concluded that wines treated with lysozyme may trigger adverse allergic reactions in susceptible individuals.<sup>12</sup>

### **Environmental concerns**

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.<sup>13</sup>

One manufacturer in Europe, Bioseutica, states that free-range hens are used for egg white lysozyme production. 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.

<sup>&</sup>lt;sup>11</sup> EFSA 2005. <a href="http://www.efsa.europa.eu/de/scdocs/doc/186.pdf">http://www.efsa.europa.eu/de/scdocs/doc/186.pdf</a>

<sup>&</sup>lt;sup>12</sup> EFSA 2011. http://www.efsa.europa.eu/en/efsajournal/doc/2386.pdf

 $<sup>^{13}</sup>$  Technical Evaluation Report. Enzymes. August 19, 2011. Compiled by ICF International.  $\underline{\text{http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5094942}}$ 

<sup>&</sup>lt;sup>14</sup> Bioseutica. Lysozyme. <a href="http://www.bioseutica.com/products/lysozyme">http://www.bioseutica.com/products/lysozyme</a>. Viewed 9/13/14.

### Essentiality; alternatives that 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.

### Results of Cornucopia's Egg White Lysozyme Survey

In September 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 (see survey as appendix I).

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. Additional results from the mailed survey will be delivered to the NOSB during oral testimony at the upcoming meeting in Louisville, Kentucky. These preliminary results are solely based on receipt of initial emails.

### Cheesemakers

To date, none of the responses from cheesemakers indicate they are using the material.

### **Winemakers**

So far, 61% of winemakers indicated they do not use the product, 30% said they did, and 7% indicated they would use it if necessary.

Winemakers came up with a number of possible alternatives, including one that suggested the use of organic egg whites. A number were adamant that, since this was used, in essence, as an antimicrobial agent (preservative), that immaculate sanitation was their secret in not requiring the use of the material.

At least one very large California winemaker (conventional/organic) held its use as imperative to their operation.

We should have a much larger sampling by the last week in October for presentation to the NOSB along with documentations of comments, from both perspectives, for the Board to consider.

### **Quality of 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."<sup>15</sup>

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." <sup>16</sup> 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 the substance. 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. 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.

### **CONCLUSION**

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

- Quality and completeness of 2011 Technical Review
- Questions about the classification as "non-synthetic"
- Allergenic concerns; need for allergen labeling
- Conventional production; animal welfare

www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5057493

<sup>&</sup>lt;sup>15</sup> NOSB. Official Minutes November 2000.

<sup>&</sup>lt;sup>16</sup> USDA, 2003. TAP Review: Enzymes, Plant, and Fungal. NOSB/National List Comment Form: Processing.

Until we can obtain this information, The Cornucopia Institute will have to **oppose the relisting of this material**. Although our preliminary survey results show that some wine- and cheese-makers depend on this material, it appears to be a minority. We will have a more complete report of survey results available at the NOSB meeting later in October.

# **L-Malic Acid - Sunset 2016**

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 made casual mention that L-malic acid could be produced naturally through double fermentation. No separate petition was made for L-malic acid and 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 and then the fumaric acid is fermented into L-malic acid. No other information about its manufacturing process is available in the TAP review.

### 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.<sup>17</sup> 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, that had L-malic acid in it. Most other manufacturers and other products use citric acid as a pH adjuster.

### **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. 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.** 

<sup>&</sup>lt;sup>17</sup> Hull P. 2010. Glucose syrups: Technology and applications. Wiley-Blackwell.

# <u>Microorganisms - Sunset 2016</u>

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. They include bacteria, fungi, yeasts, viruses, and bacteriophages and 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). Some chemicals (preservatives) may be added to protect the microorganisms from oxidation, including sodium chloride, calcium chloride, and others. Carriers are added, which may be organic or non-organic (dried milk, soy, wheat, etc.).

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 (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.<sup>18</sup>

### **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

<sup>&</sup>lt;sup>18</sup> 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.

relisting microorganisms. These are particularly troublesome issues in meeting the OFPA's environment and human health criterion.

We also 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. Therefore, The Cornucopia Institute cannot support a relisting of microorganisms at this time.

# **Activated Charcoal - Sunset 2016**

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.<sup>19</sup> 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. Activated charcoal has utility in processing organic food; after

<sup>&</sup>lt;sup>19</sup> AMS. Activated Carbon. Processing. 2002 TAP Review <a href="http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5066960">http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5066960</a>

reviewing a new TR, unless new risks were uncovered, it is likely Cornucopia would support its relisting. The Cornucopia Institute remains **neutral on this substance at this time**.

# Peracetic Acid - Sunset 2016

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,<sup>20</sup> 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 effective than the alternatives in many situations.<sup>21, 22</sup> Other research shows that it is important to alternate disinfectants so that you don't build up resistant pathogens.<sup>23</sup> 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**.

<sup>&</sup>lt;sup>20</sup> http://www.epa.gov/pesticides/chem\_search/cleared\_reviews/csr\_PC-000595\_12-Jul-07\_a.pdf

<sup>&</sup>lt;sup>21</sup> 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.

<sup>&</sup>lt;sup>22</sup> 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.

<sup>&</sup>lt;sup>23</sup> 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.

# <u>Boiler Chemicals: Octadecylamine,</u> <u>Diethylaminoethanol, and Cyclohexylamine –</u> <u>Sunset 2016</u>

The Cornucopia Institute opposes the relisting of the boiler chemicals octadecylamine, diethylaminoethanol, and cyclohexylamine because they fail all three OFPA criteria: health and environmental impacts, essentiality, and compatibility with organic handling practices.

Cyclohexylamine, diethylaminoethanol, octadecylamine are currently listed for use only as boiler water additives for packaging sterilization.

The last TAP review was in 2001 for each additive. The Cornucopia Institute recommends that a current TAP review be completed in order to assure the Board that 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.

We recommend that the full Board discuss and vote on whether or not to relist these materials, as required by law. Therefore, we recommend the Handling Subcommittee remove octadecylamine, diethylaminoethanol, and cyclohexylamine from the National List so that the full Board can vote on these materials.

### 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.
- 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.
- ➤ Handlers with entirely organic operations may still have difficulty with acid attack in the steam lines and require a volatile amine for proper maintenance.
- Ammonium hydroxide, which was petitioned to be added to the National List as a boiler additive in 2012, is 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 need further discussion:

### 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 a less toxic alternative.

# 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.<sup>24</sup>

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

None that we are aware of since ammonium hydroxide, as an alternative, is not yet on the National List.

### 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 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 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

<sup>&</sup>lt;sup>24</sup> http://www.steamforum.com/pictures/water%20treat%20Boilers%281%29.pdf

this is the best solution to maintain boiler health while minimizing the impact to the environment and humans.

In addition, we believe that the full Board should discuss and vote on whether or not to relist these materials. Therefore, we recommend that the Handling Subcommittee motions to remove octadecylamine, diethylaminoethanol, and cyclohexylamine from the National List so that the full Board can consider these materials, as required by law.

# Sodium Acid Pyrophosphate - Sunset 2016

Sodium acid pyrophosphate (SAPP) is listed for use as "a leavening agent only" under §205.605(b), synthetics allowed. It was added to the National List on September 12, 2006. 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."<sup>25</sup> 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." 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.<sup>27</sup>

### 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.<sup>28</sup>

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.<sup>29</sup> 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.

<sup>&</sup>lt;sup>25</sup> NOSB Handling Committee Recommendation 2009.

http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5081509

<sup>&</sup>lt;sup>26</sup> 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

<sup>&</sup>lt;sup>27</sup> NOSB Committee Recommendation. April 2011

http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5091720

<sup>&</sup>lt;sup>28</sup> U.S. Food and Drug Administration. April 2013. Select Committee on GRAS Substances (SCOGS) Opinion: Sodium acid pyrophosphate.

<sup>&</sup>lt;sup>29</sup> The National Academies. 1997. Dietary Reference Intakes for Calcium, Phosphorus, Magnesium, Vitamin D, and Fluoride.

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.<sup>30</sup>

### Essentiality; alternatives that 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 organic baked goods would no longer be available because" a satisfactory alternative does not exist. <sup>31</sup>

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 may fail the environment and essentiality criteria, but without a completed checklist, this remains to be understood. **Without further information, The Cornucopia Institute cannot support the relisting of this material at this time.** 

<sup>&</sup>lt;sup>30</sup> NIH. Medline. Phosphorus in the diet. September 2014.

<sup>&</sup>lt;sup>31</sup> National Organic Program Sunset Review 2011.

### <u>Tetrasodium Pyrophosphate – Sunset 2016</u>

Tetrasodium pyrophosphate (TSPP) was added to the National List under §205.605(b) on September 12, 2006, with the notation "for use only in meat analog products." The NOSB recommended relisting of TSPP at the sunset review in November 2009.<sup>32</sup>

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.

#### 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.<sup>33</sup> 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."<sup>34</sup>

### Essentiality; alternatives that 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 experience in processing, 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."

http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5081510

http://toxnet.nlm.nih.gov/cgi-bin/sis/search/a?dbs+hsdb:@term+@DOCNO+854

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=182.6789

<sup>&</sup>lt;sup>32</sup> AMS Sunset of Tetrasodium pyrophosphate. 2009.

<sup>&</sup>lt;sup>33</sup> NIH. Toxnet.

<sup>&</sup>lt;sup>34</sup> FDA. PART 182. Substances Generally Recognized as Safe.

### **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.<sup>35</sup> The report appears inconclusive, yet TSPP passed a full NOSB vote for listing in April 2004.

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 others, possibly this case, undue influence by corporate agribusiness, including from individuals inappropriately and/or illegally appointed to the Board, quite possibly has 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 non-meats.

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.<sup>36</sup> 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.

<sup>&</sup>lt;sup>35</sup> Tetrasodium Pyrophosphate. TR 2002. Compiled by Organic Materials Review Institute. http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5105016

<sup>&</sup>lt;sup>36</sup> Tetrasodium Pyrophosphate. TR 2014. Compiled by USDA, AMS, Agricultural Analytics Division. http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5108712

### **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 supports the removal of this substance.** 

# COMPLIANCE, ACCREDITATION, CERTIFICATION SUBCOMMITTEE

# **Discussion Document: Assessing Soil Conservation Practices**

Maintaining or improving the natural resources of a farm, namely soil and water quality, is a foundational tenet of organic agriculture, OFPA, and the federal organic regulations. The Compliance, Accreditation, and Certification Subcommittee (CAC) has been asked by the National Organic Program (NOP) to develop this discussion document presumably in an effort to assure certifiers are clear about how to enforce the soil health aspects of the organic regulations.

There are two main ways that certifiers work to ensure that organic producers are protecting their natural resources. The first is the written Organic System Plan (OSP) that includes sections describing how the producer intends to protect or enhance soil and water quality. The second is the annual inspection in which the certification staff visits the operation to verify that the farm is properly implementing the OSP.

There are flaws with the current system. First, some Organic System Plans say very little about what kind of soil and water conservation practices are going to be implemented. If one producer states they will do no-till, frost-seeding of cover crops, and add compost each year while a neighboring producer of the same crop states they will simply apply conventional, composted chicken manure (purchased off the farm), who is properly following the regulations? Who is doing enough? If the certification staff does not have the training or education to understand soil ecology, they might not even understand the difference between these two management systems.

The other flaw is the annual inspection, which is a mere one-day snapshot out of 365 as to what that operation looks like. If the inspection takes place in the summer, the inspector may not see soil erosion happening later that fall or in the early spring. If the dairy is visited in July, the inspector may not see the problematic application of manure onto frozen ground the past January. Likewise, just because a group of organic pigs tore up a pasture during a moist May does not mean there will be observable soil erosion come that November. Certain activities may not look good while they are occurring but are actually restorative when done right. How would a certifier know this when they only see things once a year?

The Cornucopia Institute's suggested solutions include the following:

- 1. The OSP should be required to be much more detailed about natural resources conservation practices and the year-round activities that they entail. Livestock producers should describe their year-round grazing plan. Crop producers should describe their year-round cropping plan. All confined animal feeding operations (CAFOs, as defined by the U.S. EPA) should describe their year-round manure management plan.
- 2. Certification staff should be well trained and versed in conservation planning. They should either have degrees in natural resources management, ecology, agronomy, hydrology, or have formal training with the NRCS in conservation planning. They must be able to read into a plan and understand what is going on and what might be missing from the plan.
- 3. When in doubt, certification staff should consult with NRCS or Soil & Water Conservation District staff about the soils and conservation issues of a particular area and if the practices proposed in an OSP are sufficient to maintain or improve those natural resources conditions.
- 4. Organic producers with CAFO permits should be required to submit their EPA or state CAFO permit along with their OSP and provide more detailed information about how they will prevent contamination of crops, soils, or water by nutrients, pathogens, heavy metals, or prohibited substance residues.
- 5. Annual inspections (along with supplemental, unannounced spot inspections) should be conducted at different seasons of the year so operations can be viewed during those different seasons. For example, the first year inspection could take place in the fall and successive years would take place in the winter, spring, and then again in the fall. Instead of every 12 months, it could happen every 15 months to account for seasonality.
- 6. Any producer who has received a local, state, or federal notice for violating any environmental laws (such as waste discharge permits, Clean Water Act, USFWS, etc.) should immediately be required to submit an updated OSP addendum on how they will rectify the situation, including a timeline. The certifier should visit the operation immediately and also once the practices have been implemented to ensure compliance. If the concerns regarding the violation are not rectified, the certifier should send a notice of non-compliance or even suspension. If a certification agency has multiple producers with environmental violations (or a single producer that received multiple violations), that certifier should have their own accreditation re-evaluated.
- 7. All organic operations, even those comprised of mainly buildings and parking lots, should be required to describe how they will actively maintain or improve the natural resources around their facility. For example, many industrial-scale egg operations are just a series of long barns surrounded by dirt roads and

parking lots. How are these operations maintaining or improving soil and water health?

- 8. Consider livestock density rules similar to those of the European Union organic regulations which determine how much stock can be contained in a given area based on nitrogen loading. Contrary to organic principles, nutrient build-up is not considered under U.S. organic law. For example, how much nitrogen and phosphorus builds up in the feedlot soil of a 10,000-cow organic dairy or on field surrounding the operation? Where do those nutrients go? How are certifiers ensuring those nutrients are not leading to pollution (of air, groundwater, surface water, or soil)? CAFO operations should be required to document how they are ensuring they are not creating nutrient pollution as a result of their operations.
- 9. In order to reduce the paperwork burden for organic producers that are already enrolled and cooperating in an NRCS program, producers should be able to submit their NRCS-approved Conservation Plan in lieu of detailed soil and water quality descriptions in their OSP.

### LIVESTOCK SUBCOMMITTEE

# **Proposal: Livestock Vaccines Made With Excluded Methods**

In November 2009, the NOSB board voted to continue to allow all vaccines for animal health and disease prevention purposes, except that vaccines made by non-excluded methods be used by organic producers *before* choosing any made by excluded methods.

However, most certifiers do not require their producers to document that the vaccines they use are not made with excluded methods. Due to labeling inconsistencies, Confidential Business Information, and a growing number of complex genetic engineering techniques, it is next to impossible for a certifier or a Material Review Organization (MRO) to determine if excluded methods were used to produce a vaccine.

As a follow-up, in 2012 the NOSB also recommended that the NOP help identify all vaccines registered with the USDA as either GMO or non-GMO and produce a list that could help certifiers and producers.

The USDA was concerned that if they created the requested list they would be implying that there is a deficiency in vaccines made with excluded methods and that there might be liability issues if there were inaccuracies in the list. **Therefore, the creation of a list has not gone forward.** 

This leaves the burden on the producers, certifiers, and MROs to figure out if a vaccine is made with excluded methods and if an alternative one exists.

This most recent discussion document put forth by the Livestock Subcommittee on August 19, 2014 asks for more guidance from the NOP on how to make a determination of whether a vaccine has been produced with excluded methods so that it is not left to the certifiers and MROs to make that determination.

The NOSB, Livestock Subcommittee, and others have invested considerable time in researching and reviewing this issue, a number of times. The Cornucopia Institute believes it is well past time that the NOP provide clear guidance based on NOSB recommendations to organic producers about which vaccines they can use, which ones they can't, and what constitutes excluded methods.

Lacking this guidance, it will be very difficult for the organic community to establish procedures discouraging the use of vaccines made with excluded methods, as it appears is required by law. Further, this issue may very well concern organic consumers if the deficiency was widely known.

### **CROPS SUBCOMMITTEE**

### **Inerts Verbal Update**

Consumers expect organic food to be produced without the use of potentially dangerous chemicals and that any chemicals used in organic products are thoroughly reviewed and approved. This expectation is legally grounded in OFPA. Inerts should not be given a free pass from the legally required review process.

The term "inerts" is misleading because they often act to increase the effectiveness of the active ingredients and may possess their own particular toxicological effects on human health or the environment. Even the EPA encourages manufacturers to use the term "other ingredients" instead of "inerts."

The current Fall 2014 agenda calls for an "update" on inerts without a document for comment. The Cornucopia Institute urges the NOP to implement the changes in the "inert" listing as recommended unanimously by the NOSB in October 2012.

The NOSB has already recommended the following language be implemented:

Replace the language at sections 205.601(m) and 205.603(e) with:

As synthetic other ("inert") ingredients in pesticide formulations as classified by the Environmental Protection Agency (EPA) for use with nonsynthetic substances or synthetic substances listed in this section that are used as an active pesticide ingredient in accordance with any limitations on the use of such substances.

- (i) Substances permitted for use in minimal risk products exempt from pesticide registration under FIFRA section 25(b);
- (ii) Reserved (for list of approved other ("inert") ingredients)

Under (ii) above, list all inerts known to be used in organic production, as determined by the Inerts Working Group each annotated with an expiration date.

Inert chemicals should never be listed without the proper review that is required by OFPA in order to uphold the integrity of organics that consumers have come to expect. The Cornucopia Institute supports the detailed comments provided by Beyond Pesticides, a leader in the field of protecting human health and the environment from the toxic effects of agrichemicals.

### <u>Discussion Document: Protecting Against</u> <u>Contamination in Farm Inputs</u>

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.

Among other contaminants, new herbicides introduced within the last 10 years are particularly problematic.

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 a variety of crop plants 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 the source of the hay fed to the animals.

In addition to herbicides and their residues in manure and compost, there are many other contaminants that can impact organic farms. These include insecticides and heavy metals, GMOs, and antibiotics. Sources of these contaminants include irrigation water, newspaper mulches, and fertilizers.

Documented examples of contamination of farm inputs include:

- Arsenic in poultry litter
- Bifenthrin insecticide in commercially available compost
- Municipal sewage sludge containing heavy metals such as arsenic, cadmium, copper, lead, chromium, mercury, nickel, selenium, zinc, molybdenum, and thallium (note: sewage sludge is banned in organic production.)
- Irrigation water containing elements toxic to plants including excessive boron and sodium, and elements toxic to plants at very low concentrations including chloride, lithium, selenium, molybdenum, fluoride, and chromium

Contaminated compost. A specific example was Green Mountain Compost facility, in Vermont, which was contaminated by persistent herbicides including aminopyralid, clopyralid, and picloram. According to the TR, "This resulted in a cost of \$270,000 for retrieving and compensating contaminated products and \$372,000 for testing and legal assistance in 2012."

The Cornucopia Institute wishes to comment on a few additional issues that were not considered in the discussion document:

- 1. **Unavoidable residual environmental contamination (UREC) levels should be established.** Though not an official part of the Final Rule, UREC is currently defined as any level of naturally occurring or synthetic chemicals found to be present in soil or agriculturally produced products that are below established tolerances. The USDA currently states that they don't have enough information to establish specific UREC levels. Therefore, certifying agents must follow the requirements in §205.662 Noncompliance procedure for certified operations and §205.671 Exclusion from organic sale, which uses 5% of EPA tolerances as thresholds.
- 2. **Farmers should not be held liable for unintentional contamination of herbicide residue.** As long as contaminant levels in the crops fall below allowable limits, the NOP should allow farmers to market products organically if they are subject to UREC. This is to encourage farmers to come forward when they suspect contamination may have occurred and provide the opportunity to address a solution.
- 3. The manufacturer of the herbicides should be held liable for losses incurred to farmers from unintentional contamination. The NOP should help establish a protocol for compensating farmers for production losses due to herbicide carry-over.
- 4. **Contamination of farm inputs is grossly under-reported in the U.S. and globally.** Farmers are not always qualified to know why crops are failing or showing reduced yields. Often, even professionals cannot 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 in place to be compensated for financial losses due to herbicide carryover, farmers are much more likely to investigate and report when contamination has occurred.
- 5. **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."

- a. Many sensitive crop plants show symptoms well below the 1 ppb level. "Only the persistent 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."
- b. It is extremely problematic that we are leaving testing in the hands of the manufacturers producing the chemicals. In past cases of herbicide contamination, regulators have been unable to identify all sources of contamination because of the lack of testing.
- 6. **Tracking herbicide-contaminated organic matter is nearly impossible.**Often organic matter goes through many hands, and information about chemicals used is lost. For example, 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 who then sells to the farmer to grow vegetables. Information may be lost in each step.
- 7. 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 weeks 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.

### **CONCLUSION**

With the increase in the use of persistent chemicals, including herbicides and insecticides, organic farmers are no longer able to trust that purchased organic matter inputs and irrigation water are free of these prohibited materials.

The Cornucopia Institute would like to recommend that the Crops Subcommittee interview experts from different specialties including herbicide manufacturers, herbicide testing facilities, farmers, and business owners whose businesses have suffered from herbicide carryover.

One of our staff members, Dr. Linley Dixon, is uniquely qualified to sit on such a panel, both because of her background as an agricultural scientist and as a farmer who, after

being impacted by herbicide-contaminated compost, completed her own exhaustive study on the hidden dangers of these incidents which are all too commonly misdiagnosed.

At present, there are insufficient testing options on a national level for detection of minute quantities of persistent herbicides in compost. The NOP is encouraged to work with the EPA, the best labs in the country, as well as the herbicide manufacturers to demand and ensure that accurate, reliable, and affordable testing is in place to identify contaminants in composts.

As new and improved detection abilities are put in place, certifiers should be required to carry out regular chemical analyses on compost produced to ensure that any material applied to crops does not contain persistent herbicides or any other contaminants.

Persistent chemicals need to be banned from production because it is nearly impossible for organic crops to be clean of these materials once they are produced. Farmers should not be held responsible for unavoidable residual environmental contamination (UREC). Liability should fall on the manufacturer of the herbicides.

### **Sulfurous Acid - Sunset 2015**

Note: The Cornucopia Institute submitted comments on Sulfurous Acid at the Spring 2014 NOSB meeting. We focus on newly updated information and analysis here.

### **SUMMARY**

At the Spring 2014 NOSB meeting, The Cornucopia Institute recommended to remove sulfurous acid from the National List mainly due to insufficient technical review and the desire to have the entire Board vote on the relisting of this material. Now, according to the latest Crops Subcommittee review, this material failed two out of three OFPA criteria (essentiality and compatibility).

It is our belief that this material might actually satisfy those two criteria but <u>not</u> the impact to human health and the environment criterion, based on the latest published science and conversations with salinity researchers in California.

We continue to believe, based on OFPA, that the full Board is required to review, discuss, and vote on whether or not to relist this material. **Therefore, we support the Crops Subcommittee's motion to remove sulfurous acid from the National List so that the full Board can consider this material**.

### Rationale:

- Further discussion is needed related to newly published research.
- ➤ Soil and water alkalinity is a growing problem and needs to be addressed through a wide range of practices that may include the use of sulfurous acid.
- > Sulfur burners are neither well researched nor regulated. The human and environmental health aspects of them are not well known.
- ➤ There are occupational health concerns with the potential for poorly maintained burners to cause human burns or fires.
- ➤ This is a difficult decision because alternative materials may not be as effective as sulfurous acid for specific applications.

### **DISCUSSION**

Sulfurous acid, an aqueous solution of sulfur dioxide, is a weak acid with the chemical formula  $H_2SO_3$ . It is added to irrigation water to lower the pH of alkaline soils and water.

High pH soils and water are found throughout the world. Indeed, the USDA estimates that between 60% and 70% of the world's cropland is alkaline in nature (over a pH of 7). For illustration, 92% of soil samples that Utah State University receives are over a pH of 7.37

Sulfurous acid is currently on the National List:

205.601 (j)(9), as a plant or soil amendment, for on-farm generation of substance utilizing 99% purity elemental sulfur per paragraph (j)(2). Elemental sulfur is currently on the National List: 205.601 (j)(2), as a plant or soil amendment.

The Crops Subcommittee brought up four items that need further discussion in their 8/20/2014 document. We will discuss what we know of the science below. These items for discussion are:

# 1. The TR contains information about environmental impacts of sulfurous acid, particularly on soil organisms;

The TR states (lines 333-336): "Overuse of sulfurous acid and subsequent acidification will cause the metabolism of microorganisms involved in compost and organic matter breakdown in treated streams and runoffs to be suppressed along the acidity gradient, and can lead to a decrease in humus production (Simon et al 2009)."

The research quoted has nothing to do with using sulfurous acid; rather, it relates to research on the ecological effects of acid rain. It is unlikely that sulfurous acid or even the alternative of elemental sulfur would ever be used in large enough quantities to over-acidify the soil or irrigation water. This is according to the TR itself, line 327.

Farmers are typically aiming for a neutral pH, not an acidic pH (unless they are growing acid-loving crops like blueberries). Irrigation water in arid environments where sodic/alkaline soils dominate is a precious resource and most organic farmers work hard to apply the correct amount. A more likely environmental impact of this technology is the inadvertent release of sulfur dioxide emissions, one of the most potent greenhouse gases. The TR says very little about this issue.

## 2. There is information on alternative materials and practices that was not considered by the Board in 2009;

The initial review stated that there were no natural substitutes or other practices. The new 2014 TR states that there are organically approved substitutes, namely organic matter, elemental sulfur, gypsum, compost, aquatic plant extracts, lignin sulfonate, liquid fish extracts, humic acids, and citric acid (in the irrigation water). Although there are no natural sources of  $\rm H_2SO_3$ , there are alternatives that serve a similar purpose: to reduce

<sup>&</sup>lt;sup>37</sup> Managing Soil pH in Utah. February 2001. Utah State University Extension. Publication AG-SO-07.

the pH of the soil or water. However, we have found in our research that many of these alternatives have challenges themselves. These include:

- **Organic matter/compost:** Most organic farmers incorporate some forms of organic matter into their soil, whether it be cover crops, crop residues, compost, organic mulches, or other materials. Organic matter can correct pH imbalances over time namely by displacing sodium cations and through the formation of organic acids like fulvic acid, 38 but excessive amounts can also tie up nitrogen, increase slug and snail habitat, 39 make crop harvest difficult, etc. It also requires moisture to break down, which arid/alkaline environments'do not have in excess. The organic matter available in arid/alkaline environments, specifically hay, straw, and horse manure, is often contaminated with persistent broadleaf herbicides, detrimental to crop production. As a result, many farmers do not have access to clean organic matter to reduce soil pH.
- **Elemental sulfur** is currently allowed in organic production and is used as both a plant nutrient and for disease control. However, its use to correct alkaline soils or irrigation water is not ideal. It often requires rates as high as 10,000 pounds per acre to cause any appreciable change to soil pH.<sup>40</sup>

The amount of sulfur required is very dependent on soil texture. This is because clay and organic matter act as a buffer, absorbing and releasing mineral ions. Relatively little sulfur is needed on sands, whereas soils high in clay or organic matter require much more.

- **Gypsum (or calcium sulfate)** is often touted as having the ability to reduce soil pH, but the science does not show it to be effective. It is effective to reduce the sodicity of soils, which is often a related problem to alkalinity.<sup>41</sup> The latest peerreviewed research indicates that when gypsum is applied to a soil it slowly dissolves into calcium and sulfate sulfur. There is no chemical reaction that happens when gypsum salt dissolves in the soil solution. With no chemical reaction, there is nothing that will make the soil pH decrease.<sup>42</sup> Gypsum does improve porosity and drainage and can help leach out excess sodium.
- Aquatic plant extracts: Although referenced as an alternative in the TR, we could find no research that shows aquatic plant extracts affect soil pH. We did find that they serve as a source of micronutrients.

<sup>&</sup>lt;sup>38</sup> Abdel-Fattah MK. 2012. Role of gypsum and compost in reclaiming saline-sodic soils. Journal of Agriculture and Veterinary Science 1 (3): 30–38.

<sup>&</sup>lt;sup>39</sup> http://www.organicresearchcentre.com/manage/authincludes/article\_uploads/iota/technical-leaflets/green-manures-leaflet.pdf

<sup>40</sup> http://www.agvise.com/educational-articles/high-soil-ph-can-we-fix-this-problem/

<sup>&</sup>lt;sup>41</sup> Abdel-Fattah MK. 2012. Role of gypsum and compost in reclaiming saline-sodic soils. Journal of Agriculture and Veterinary Science 1 (3): 30–38.

<sup>42</sup> http://vric.ucdavis.edu/pdf/Soil/ChangingpHinSoil.pdf

- **Lignin sulfonate** is a synthetic substance allowed in organic production as a soil amendment (dust suppressant, chelating agent, or floatation agent). It is not approved as a pH adjuster and cannot be considered an alternative without adding it to the List.
- **Liquid fish extracts:** There is no evidence that liquid fish extracts affect soil pH. They are approved in organic production as a fertilizer.
- **Humic acids:** There is little science that shows that humic acids affect pH, but they do appear to improve Cation Exchange Capacity (CEC), which can correct some of the problems associated with a high pH.
- **Citric acid** can be used in irrigation water, although it is very expensive to use in large enough quantities to affect water pH.

# 3. It appears that sulfurous acid might be used to correct the impacts of unsustainable irrigation practices;

Many agricultural practices are used to correct the impacts of unsustainable irrigation and soil management practices. Organic farmers are already required to maintain and conserve soil and water resources. It is likewise incumbent upon organic growers to attempt to prevent environmental problems rather than using synthetic materials to remediate them after the fact (just as livestock producers provide lower stress and healthier environments rather than depend on antibiotics and other drugs).

As industrial-scale production, of some commodities, has shifted to arid regions of the U.S., for economic reasons, it becomes challenging to differentiate the use of sulfurous acid for crops produced to feed an indigenous or local population. This situation is further complicated by that fact that somewhere between 60% and 70% of the world's arable ground is alkaline and that percent is increasing.

## 4. The use of sulfurous acid is not permitted in organic agriculture in other countries.

It is true that in Canada, the EU, and Japan, all countries that have their own organic regulations, sulfurous acid is not mentioned as an approved substance. It should be pointed out that most of those countries do not have large amounts of arid, alkaline land so the need for this input is considerably less and thus there has been little effort to get it approved. Mexico, a country with a considerable amount of arid, alkaline soils, has recently approved sulfurous acid for use in organic agriculture.

### Human health and the environment

Julie Escalera of the University of California–Riverside, under the direction of Dr. Chris Amrhein, has been researching reclaiming alkaline soil in Southern California. Her latest research led her to the Coachella Valley, where she worked with growers utilizing sulfur

burners to reclaim alkaline soils. Although her research found that sulfurous acid did have some effectiveness removing salts when compared to sulfuric acid or gypsum, irrigation leaching was the most effective strategy in this particular location due to the high calcium content of the soil.<sup>43</sup> As mentioned above, over-irrigating is often not an option in areas with drought, water restrictions, high water costs, or where growers are not allowed to have visible run-off. Yet leaching salts below the root zone is an effective strategy to deal with excess salts and can be used in certain locations.

Another sulfurous acid researcher we contacted (who requested anonymity) said, "I haven't been able to locate any regulations on the SAG equipment, maximum emissions, or fire controls. After being walked through the installation of a unit I did not see any safety measures to prevent fire and/or burns or on how the scrubbers are managed to prevent toxic levels of sulfur dioxide from accumulating." This researcher went on to express surprise that sulfurous acid was ever approved for use in organics due to the limited amount of research on both its efficacy and its safety.

Cornucopia Institute staff researched both U.S. EPA and California Department of Air Quality regulations and found none that pertain to sulfur burners. A follow-up phone call to the San Joaquin Valley Air Board confirmed that unless the sulfur burners are emitting more than two pounds of sulfur dioxide daily, they fall under a "low emitting unit" exemption. The staff person that took the phone call in Bakersfield, California, had never even heard of sulfur burners. This technology is flying below the radar of regulators yet has the potential to emit sulfur dioxide emissions and potentially cause human burns and fires if not maintained properly.

For these reasons, The Cornucopia Institute believes that sulfurous acid fails to pass the human health and environment criterion of OFPA.

### **CONCLUSION**

Although sulfurous acid does appear to have some usefulness in solving the widespread problems of soil and water alkalinity, more research is needed to understand its modes of action in different soils, the potential emissions of sulfur dioxide into the air, and the occupational safety hazards of sulfur burners. The technology is still fairly new, such that there aren't even rules about them within state air resources boards or the U.S. EPA. A more thorough Technical Review should delve into these issues.

Due to the controversial nature of this substance and lack of comprehensive information, we recommend that the full Board discuss this material (as the law requires with all sunsetting materials). Therefore, we support the Crops Subcommittee's motion to remove sulfurous acid from the National List because it fails the human health and environmental criteria of OFPA.

<sup>43</sup> Escalera J. 2012. Soil Science Society of America annual meeting poster: Comparison of Gypsum, Sulfuric Acid, and Sulfurous Acid for the Reclamation of Salt Affected Soils.

### **Sodium Carbonate Peroxyhydrate - Sunset 2015**

Note: The comments below were provided for the Spring 2014 NOSB meeting. We are providing them again to reiterate our stance.

### **SUMMARY**

**Do not renew the listing of sodium carbonate peroxyhydrate** on the National List under §205.601 Synthetic substances allowed for use in organic crop production.

### Rationale:

- Use of SCP for aquatic plants must be evaluated.
- > SCP is harmful to the environment.
- ➤ Alternatives are available for control of algae.
- SCP does not fit any OFPA categories.
- ➤ International standards do not allow SCP in crop production.
- ➤ High-quality contractors should be chosen to prepare TRs.

### DISCUSSION

Sodium carbonate peroxyhydrate (SCP) is made from hydrogen peroxide and sodium carbonate. It was petitioned in 2006 by BioSafe Systems to be used as an **algaecide** in irrigations systems and natural waterbodies.

SCP is currently on the National List:

- §205.601 (a) As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems.
- (8) Sodium carbonate peroxyhydrate—Federal law restricts the use of this substance in food crop production to approved food uses identified on the product label.

OMRI lists the following products containing SCP:

GreenClean Granular (50% SCP and 50% other ingredients)
GreenClean Pro (85% SCP, 15% other ingredients)

The 2012 label for GreenClean Pro states that it is a "**bacteriocide, fungicide, algaecide**. DANGER: Corrosive. Causes irreversible eye damage. Harmful if swallowed, inhaled or absorbed through skin."<sup>44</sup> [emphasis added]

The Crops Subcommittee, in 2007, voted against adding SCP to the List (0 yes, 5 no), because SCP did not satisfy evaluation criteria 1, 2, or 3. The checklist verified that SCP was harmful to the environment, not essential because alternatives are available, and not consistent with organic production and handling.

**Despite all of those concerns, at the November 2007 NOSB meeting, the full Board approved SCP for addition to §205.601 for use as an algaecide**. One of the reasons given for approving this substance was the possibility that SCP could replace the use of copper sulfate in rice. Given the fact that the first subcommittee affirmed that SCP violates all evaluation criteria, we believe it essential at this time for the Crops Subcommittee to once again bring SCP to the full Board for review and vote.

The following discussion outlines reasons why SCP should be removed from the National List. Some of these reasons are not **new**; they are the same reasons that led to the initial rejection of this petition. We believe they are still valid. The meeting proposals drafted by the NOP indicate that they ask only for **new** information. We encourage the Board members to consider <u>all relevant information</u>. Board members represent the organic community, not the NOP.

OFPA cannot be superseded by NOP memorandum changing the sunset process. It remains the right and responsibility of NOSB members to carry out the law by fully reviewing all materials on the National List every five years.

### The entire Board should vote on the relisting of sodium carbonate peroxyhydrate

When SCP was initially approved, a robust sunset policy was in place. The Board members who approved SCP were assured that it would be thoroughly reviewed and voted on by the entire NOSB in five years. Those Board members believed that it would automatically be removed from the National List, unless a majority of the NOSB voted in favor of renewing the listing.

Under the new sunset process directed by the NOP, most of the Board members have been disenfranchised. The Crops Subcommittee may choose to renew SCP in their subcommittee meeting, thereby preventing their fellow Board members from having a voice in the matter. We urge the Crops Subcommittee **not** to renew SCP. Instead, we urge them to develop a proposal to remove it as part of their preliminary review. This is the only way to ensure that the full Board reviews this material, as required by OFPA and as practiced successfully for more than a decade of NOSB meetings.

 $<sup>^{44}</sup>$  2012 Label for Greenclean Pro. Downloaded from  $\underline{\text{http://www.biosafesystems.com/documents/GreenCleanPRO\%20Specimen\%20Label.pdf.}}$ 

Cornucopia strongly urges the Crops Subcommittee to recommend against relisting of sodium carbonate peroxyhydrate, by preparing a formal motion for the next Board meeting.

### Use of SCP for aquatic plants must be evaluated

Recently, the NOP clarified that aquatic plant production is allowed under USDA organic regulations. A Policy Memorandum issued on September 12, 2012 stated:

This policy memorandum is issued as a reminder that aquatic plants and their products may be certified under the current USDA organic regulations. Certifiers and their clients may use the USDA organic regulations, including the National List ... 205.601 – 205.602, as the basis for production and certification of cultured and wild crop harvested aquatic plants.

When the NOP chose to allow aquatic plant production, and to allow the use of synthetic materials on §205.601 that had been approved only for terrestrial crop production, the NOP allowed the use of SCP in a way that was not approved by the NOSB.

A review by the entire Board is needed to clarify <u>all</u> uses of SCP.

### SCP is harmful to the environment

The product label states that SCP is a **bacteriocide**, **a fungicide**, **and an algaecide**. When applied in an aquatic environment, such as a pond or rice field, its action is not limited to the intended use—to kill algae. It also acts as a **general biocide**, killing bacteria and fungi. This is not consistent with the pest control practices of successful organic farmers, who use pest control products that have the least damage to non-target species. If released into natural waterbodies, SCP could cause undue ecological damage because of its broad-spectrum abilities.

### Alternatives are available for control of algae

The TR mentions several ways to reduce algae in ponds and rice paddies:45

- ➤ Rice straw
- Barley straw
- ➤ Allelopathic plants
- ➤ Herbivorous fish

### Sodium carbonate peroxyhydrate does not fit any OFPA categories

All materials added to the National List must contain an active synthetic ingredient in one of the OFPA categories. SCP fails this essential requirement; therefore, it should never have been approved. **This is not new information; it was noted by the Crops** 

<sup>&</sup>lt;sup>45</sup> AMS Agricultural Analytics Division. 2014. TER Sodium Carbonate Peroxyhydrate (Crops) Lines

**Subcommittee in the original checklist**. However, it remains a valid reason to remove SCP from the National List.

### International standards do not allow SCP in crop production

The raw materials to manufacture SCP, hydrogen peroxide and sodium carbonate, are allowed by some international standards for disinfection of processing equipment and buildings.

The use of SCP for cleaning irrigation lines, for use in rice production, or for addition to natural waterbodies are fundamentally different uses than disinfection of processing equipment. SCP is not listed for crop production by Canada, Japan, or the European Economic Community. It is not listed by CODEX or IFOAM.

### High-quality contractors should be chosen to prepare TRs

The current Technical Review for SCP was prepared by the USDA Agricultural Marketing Service (AMS) Agricultural Analytics Division. The TR was requested by the Crops Subcommittee in February 2013, and the final copy was dated January 15, 2014, almost a year later. The initial TR was deemed insufficient by the Crops Subcommittee and had to be returned to the contractor for additional research. Due to the fact that they were not vetted through the open bidding process, the apparent lack of technical qualifications, and the inordinate amount of time required to complete the TR, we request that the NOP not use this contractor again.

### **CONCLUSION**

**Do not renew the listing of sodium carbonate peroxyhydrate** on the National List under §205.601 Synthetic substances allowed for use in organic crop production because SCP is harmful to the environment, is not essential because alternatives are available, and not consistent with organic production and handling..

### <u>Aqueous Potassium Silicate – Sunset 2015</u>

Note: These comments were provided for the Spring 2014 NOSB meeting. We are providing them again to reiterate our stance.

### **SUMMARY**

**Do not renew the listing of aqueous potassium silicate** on the National List under §205.601 Synthetic substances allowed for use in organic crop production.

#### Rationale:

- ➤ Initial approval was based on insufficient review.
- > Specific use—fertilizer, disease control, insecticide—should be clarified.
- > Alternatives are available.
- > Information is needed on accumulation of silica in plants.
- ➤ International standards do not allow aqueous potassium silicate in crop production.
- ➤ High-quality contractors should be chosen to prepare TRs.

### **DISCUSSION**

Aqueous potassium silicate is currently on the National List under  $\S 205.601$  (e)(2) and (i)(1):

- (e) As insecticides (including acaricides or mite control).
- (i) As plant disease control.

Both listings state: Aqueous potassium silicate—the silica, used in the manufacture of potassium silicate, must be sourced from naturally occurring sand

APS was petitioned by PQ Corporation, manufacturers of the formulated product Sil-Matrix. The label attached to the petition states that the product is 29% potassium silicate, 71% other ingredients. The potassium silicate used in agriculture contains potassium carbonate and silicon dioxide in a ratio of 2.5 to 1.46

When aqueous potassium silicate (APS) was initially approved, a robust sunset policy was in place. The Board members who approved APS in 2007 assumed that it would be thoroughly reviewed by the entire Board every five years. They believed that the entire

<sup>&</sup>lt;sup>46</sup> AMS AAD. 2014. TER Aqueous Potassium Silicate (Crops). Lines 87-88.

NOSB would have the opportunity to vote on removal of any material from the National List, if it proved to be incompatible with organic production principles.

Under the new sunset process directed by the NOP, most of the Board members have been disenfranchised. The Crops Subcommittee may choose to renew APS in their subcommittee meeting, thereby preventing their fellow Board members from having a voice. There is only one way to ensure that the full Board reviews this material, as required by OFPA, and as practiced successfully for more than a decade of NOSB meetings. "The NOSB subcommittees can develop proposals to remove substances as part of their preliminary review." If the subcommittee chooses not to develop a proposal to delist, the other Board members will have no opportunity to voice their opinions and vote.

Cornucopia strongly urges the Crops Subcommittee to develop a proposal that recommends against relisting of aqueous potassium silicate, by preparing a formal motion for the next Board meeting.

Due to the new NOP sunset rules, the only way that the Crops Subcommittee can ensure that the Board conducts a full review of APS is to vote in favor of a proposal for removal.

There are several reasons why this material requires a review by the full Board to determine whether it is compatible with organic production.

### Initial approval was based on insufficient review

The PQ Corporation submitted a petition for aqueous potassium silicate in 2002 and substantially revised the petition in June 2006. The 2006 petitioned uses were:

- > Plant disease control
- ➤ Insecticide/miticide
- ➤ Soil/plant amendment, for hydroponic use only

A TAP review was compiled by UC SAREP (the University of California Sustainable Agriculture Research and Education Program) in 2003. **This review addressed petitioned use for disease control and as a soil amendment. It did not address insecticide use.** 

In the TAP review from 2003, two reviewers felt APS should be prohibited. One of these reviewers cited the nature of potassium silicate as a **highly soluble synthetic fertilizer**, and questioned its effectiveness as a fungicide. The other dissenting reviewer raised similar concerns, questioning the need for silica amendments in organic systems and the legitimacy of supporting evidence. The third reviewer was in favor of adding the substance to the List, with annotations. Clearly, **two of the three experts had serious** 

<sup>&</sup>lt;sup>47</sup> Notification of sunset process, document number AMS – NOPP – 13 – 0057; NOP – 13 – 03.

**reservations about this material**. That, in itself, should signal that a complete review is needed at this time.

Regarding the fungicidal activity, a TAP reviewer commented:<sup>48</sup>

"Unfortunately, there is not convincing evidence that potassium silicate will be even as effective as the alternatives, and its mode of action is not understood. These are important considerations. Sulfur and copper are allowed synthetics because, although they have some non-target toxicity and environmental troubles, they have a well-understood mode of action and breakdown products, have been used by organic farmers for a long time, and are proven effective. Potassium silicate does not have significant non-target toxicities, environmental risks or breakdown products, but does have a poorly understood mode of action, a short history of use, and has not been proven widely effective."

In 2007, the Crops Subcommittee considered three uses of APS and voted as follows:

- ➤ Insecticide Yes: 1, No: 3, Absent: 2
- ➤ Plant disease control Yes: 1, No: 3, Absent: 2
- Plant or soil amendments (for hydroponic use) Yes: 0, No: 4, Absent: 2

They determined that APS fails categories 2 (essentiality) and 3 (compatibility).

At the November 2007 meeting, the NOSB approved the addition of APS to the National List. The rationale to approve was based on testimony from the petitioner and interested stakeholders at the meeting. APS was added to the List in 2010.

### Specific uses should be clarified

The label for aqueous potassium silicate states that it can be used to control fungal diseases and certain insects. However, it does not kill fungi; instead, it functions by strengthening the cell walls of plants so that the fungi cannot penetrate the plant epidermis. The silicon remaining on the plant surface kills certain insects.

APS also functions as a fertilizer, in which case it should be listed under §205.601 (j) As plant or soil amendments. Clearly the product provides silica, but it also provides synthetic potassium, as noted above. The petition specifically requested use as a hydroponic fertilizer, for  $K_2O$  (potassium) supplementation. Recently, the NOP clarified that hydroponic production is allowed under USDA organic regulations; therefore, we assume that APS is currently allowed as a synthetic source of potassium in hydroponic production. At the time that APS was reviewed by the NOSB, in 2007, hydroponic production was not allowed by organic standards. In 2008, the NOSB reviewed hydroponic production, and recommended that it should be prohibited in organic production. When the NOP chose to allow hydroponic production, disregarding the

<sup>&</sup>lt;sup>48</sup> UC SAREP. 2003. TAP Review Potassium Silicate.

recommendation of their advisory board, the NOP allowed the use of APS in a way that was not intended.

A review by the entire Board is needed to clarify all uses of APS.

### Alternatives are available

Organic production is based on the fundamental principle of feeding the soil with natural minerals to maintain plant health and resistance to insect infestations. If natural minerals are not sufficient, there are numerous synthetic plant and soil amendments on the National List. There are also many substances used as plant disease and insect control that have been used for a long time and are well understood.

Organic farmers also use management practices that maintain plant health, such as avoiding high nitrogen fertilizers which encourage fast but weak plant growth.

Natural sources of silica soil amendments are commercially available to U.S. farmers (based on a recent Internet search), including granite dust, bentonite, greensand, azomite, and diatomaceous earth. Standards written by Canada, Japan, EEC, CODEX, and IFOAM mention natural sources of silica. They do not mention the use of aqueous potassium silicate.

### Information is needed on accumulation of silica in plants

Use of APS for disease and insect control may entail multiple applications of a potassium silicate over the course of the growing season, and over the course of many growing seasons. This increases potential for soil accumulation of silica, but the effects are not well understood. There may be need for an annotation stating that silica should be used in a manner that does not cause accumulation in the soil, similar to the restriction on the use of copper for disease control.

### High-quality contractors should be chosen to prepare TRs

The 2014 Technical Review for aqueous potassium silicate was prepared by the USDA Agricultural Marketing Service (AMS) Agricultural Analytics Division. The TR was requested in April 2013, and the final copy was dated January 6, 2014, nine months later. The initial TR was deemed insufficient by the Crops Subcommittee and had to be returned to the contractor for further work. Due to the poor quality of their work and the inordinate amount of time required to complete the TR, we request that the NOP not use this contractor again.

### **CONCLUSION**

When aqueous potassium silicate was first petitioned, the Crops Subcommittee determined that it was not essential and it was not compatible with organic agriculture.

Nonetheless, it was approved, with the assumption that it would be removed from the National List after five years, unless a majority of the members voted to relist it.

**Aqueous potassium silicate should not be renewed** on the National List under §205.601 Synthetic substances allowed for use in organic crop production because it is non-essential and nonsynthetic alternatives are available.

### Ferric Phosphate - Sunset 2016

### **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, there is limited research to indicate that ferric phosphate is effective as a slug and snail bait without EDTA. In addition, all of the ferric phosphate slug and snail baits currently marketed in the U.S. contain EDTA in their formulations.

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.

### Rationale:

- ➤ The TAP review, dated 2012, appears unbiased and thorough. It indicated that ferric phosphate is likely not effective alone as a slug and snail bait as it is currently listed on the National List.
- ➤ EDTA, present in all slug and snail baits in the U.S., is toxic to soil microorganisms and non-target species, including earthworms, plants, and can contribute to ground water contamination. It is persistent (does not degrade quickly) in the environment and raises concerns for human health and calcium absorption as well. 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 four 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 materials that allow ferric phosphate to work as an effective molluscicide. EDDS is less persistent but has unknown effects on soil microbial communities.

# 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.

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

# 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.

# 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.

### **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.

### <u>Hydrogen Chloride - Sunset 2016</u>

### **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.

Though hydrogen chloride (HCl) fails two of OFPAs three criteria — health and environmental impacts and compatibility with organic practices — HCl **may be** essential until high quality mechanical delinters are commercially available. However, the TR does not address this issue.

Hydrogen chloride is listed as a synthetic at §205.601 for the removal of lint from cottonseeds so that they can be mechanically planted. Hydrogen chloride gas is highly corrosive and extremely hazardous. Less corrosive acids (lactic, sulfurous, and acetic acid) are also used for cottonseed delinting.

More importantly, mechanical delinting is in the final stages of development.  $^{49, 50}$  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.  $^{51}$ 

### Rationale:

- ➤ The TAP review, dated 2003, is very outdated and does not discuss effectiveness of alternatives or new developments in mechanical delinting.
- Lactic, sulfurous, and acetic acid are less toxic alternatives (hydrogen chloride is a more corrosive acid). There is no discussion in the TR of how alternative acids compare in terms of efficacy and in different regions of the country where cotton is grown. Sulfuric acid is currently used in the South.
- ➤ Mechanical delinting eliminates the need to use any acid. There is no mention of the current research into mechanical delinting in the TR.

<sup>49</sup> http://www.ferrooiltek.com/product\_fc200delinter.html

<sup>50</sup> http://cottonfarming.com/home/issues/2014-05/Pg-Feature-Cotton-Board-sm.pdf

<sup>&</sup>lt;sup>51</sup> http://www.cottonfarming.com/research-promotion/mechanical-delinting-of-cottonseed-has-promise/

- L.T. Kincer manufactures both a saw delinter and a dilute sulfurous acid delinter. The effectiveness of these delinters 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.

### **DISCUSSION**

Hydrogen chloride is used to remove lint from cottonseeds so that seeds can be mechanically planted. 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.<sup>52</sup>

### 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.<sup>53</sup>

#### Alternatives exist

The Cornucopia Institute believes that the TR is deficient in its discussion of alternatives. The question of suitability of alternative weaker acids (lactic, sulfurous, and acetic acid) was not addressed nor was the possibility of mechanical delinting. If these are not satisfactory techniques for cotton delinting, then more extensive documentation of the inadequacies of these alternate methods must be documented.

USDA/ARS Researcher Greg Holt should be consulted to determine what is needed to bring mechanical delinting from the research stages into commercial production.

### **Environmental concerns**

The TAP review indicates that approximately 8 to 12 pounds of hydrogen chloride are required in the delinting process of 1 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

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<sup>52 &</sup>lt;a href="http://pubchem.ncbi.nlm.nih.gov/summary/summary.cgi?cid=313#x27">http://pubchem.ncbi.nlm.nih.gov/summary/summary.cgi?cid=313#x27</a>

<sup>53</sup> http://www.epa.gov/ttn/atw/hlthef/hydrochl.html

of these gases, which the agency defines as Hazardous Air Pollutants.<sup>54</sup> 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.

### **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 discuss current research into mechanical delinting and alternative acids. Though HCl is hazardous to humans and the environment, it may be deemed essential if the current research into the production of mechanical delinters is not ready for commercial application.

The Cornucopia Institutes remains **neutral** on whether or not to relist hydrogen chloride until a new TR addresses the issue of commercial availability of mechanical delinting.

In addition, we believe that it is the role of the full Board to discuss and vote on relisting of all materials. Therefore, we recommend that the Crops Subcommittee vote to remove hydrogen chloride from the National List so that the full Board can consider this material after a new TR is completed.

4 Ibid.			

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### **APPENDIX I**



# Survey on the Use of Egg White Lysozyme in Organic Cheese Production

The National Organic Standards Board is reviewing the use of Egg White Lysozyme as part of the Sunset process to determine if the non-organic material should be reapproved for use in organics.

The Cornucopia Institute is surveying organic cheesemakers about the use of this substance in the cheese making process. We intend to share the results with members of the board as part of their decision making process at the next NOSB (please return this survey ASAP as the deadline for written comments is October 7). You can email me at wfantle@cornucopia.org or mail this to The Cornucopia Institute, PO Box 126, Cornucopia, WI 54827 or FAX it to 866-861-2214.

Would you please answer the following few short questions to help us gather information for the NOSB.

- 1. Do you use Egg White Lysozyme?
- 2. If you use Egg White Lysozyme, what is the purpose of its use in your application?
- 3. Are there alternatives (materials or management practices) to the use of Egg White Lysozyme that you employ, and, if so, what are they?

Please feel free to share any other comments. If you would like your response is to remain anonymous please let us know and we will respect that.

Thank you for your help.

Sincerely,

Will Fantle, Codirector



### Survey: Egg White Lysozyme in Organic Wine Production — Essential?

The National Organic Standards Board (NOSB) is reviewing the use of Egg White Lysozyme as part of the Sunset process to determine if the non-organic material should be reapproved for use in organics.

The Cornucopia Institute is surveying organic vintners about the use of this substance in the winemaking process. We intend to share the results with members of the board as part of their decision making process at the next NOSB meeting (please return this survey ASAP as the deadline for written comments is October 7). You can email me at wfantle@cornucopia.org or mail this to The Cornucopia Institute, PO Box 126, Cornucopia, WI 54827 or FAX it to 866-861-2214.

Would you please answer the following few short questions to help us gather information for the NOSB.

- 1. Do you use Egg White Lysozyme?
- 2. If you use Egg White Lysozyme, what is the purpose of its use?
- 3. Are there alternative materials or management practices to the use of Egg White Lysozyme that you employ, and, if so, what are they?

Please feel free to share any other comments you might have concerning this material. If you would like your response to remain anonymous please let us know and we will respect that.

Thank you for your help.

Sincerely,

Will Fantle, Codirector