



POLICY & ACTION FROM CONSUMER REPORTS

October 4, 2018

U.S. Department of Agriculture
Agricultural Marketing Service
National Organic Program
c/o Michelle Arsenault, Special Assistant
1400 Independence Ave., S.W.
Washington, DC 20250

Submitted via www.regulations.gov.

**Comments of Consumers Union to the Agricultural Marketing Service
on the Fall 2018 Meeting of the National Organic Standards Board
Docket No. AMS-NOP-18-0029**

By

Michael Hansen, Ph.D., Senior Scientist
Charlotte Vallaey, M.S., Senior Policy Analyst

Consumers Union, the policy division of Consumer Reports, welcomes the opportunity to submit written comments to the U.S. Department of Agriculture (USDA) Agricultural Marketing Service (AMS) on the proposals and discussion documents for the fall 2018 meeting of the National Organic Standards Board (NOSB) in Saint Paul, Minnesota.

Consumer Reports is an independent, nonprofit organization that works side by side with consumers to create a fairer, safer, and healthier world. For 80 years, we have provided evidence-based product testing and ratings, rigorous research, hard-hitting journalism, public education, and steadfast policy action on behalf of consumers' interests. We work with consumers in many areas, including efforts to create a safe, sustainable, and transparent food system.

One of our areas of focus is food labels, which should be clear, honest, and transparent. We evaluate and rate food labels, including the USDA Organic seal, to empower consumers with knowledge to make better and more informed decisions when shopping for food. Our information and ratings are available to consumers online at www.greenerchoices.org.

In Consumer Reports' publications, in both print and online, we discuss the value of the USDA Organic label when shopping for food. We explain to consumers that the USDA Organic label is backed by federal law and regulations that set a uniform and consistent standard for what can be labeled "organic." We tell consumers that the federal organic standards are comprehensive, promote sustainable agriculture, and aim to minimize negative impacts on the environment and human health.

This assurance that a consistent set of strong standards is met is critical to the integrity of the USDA Organic seal. When the standards backing the organic label fall short, we advocate for the USDA to strengthen them. Since the National Organic Standards Board, a federal advisory board established by the Organic Foods Production Act (OFPA) of 1990, makes formal recommendations to the Secretary of Agriculture on changes to the federal organic standards, we consistently provide written and oral comments to the NOSB.

Preserving the Integrity of the Organic Label

The value of the organic label lies in the strength of the Organic Foods Production Act (OFPA) and USDA organic regulations, which promise consumers a consistent standard for organically produced foods. OFPA and the regulations also create a meaningful process with strict limits for determining what can and cannot be used in organic food production. Proper material review by the National Organic Standards Board (NOSB), consistent with the process outlined in OFPA, is a critical component of ensuring the continued integrity of the organic label.

Meeting Consumer Expectations - Survey Data

At Consumer Reports, we conduct consumer surveys, which are second in size only to the U.S. Census. Our surveys are developed by the National Research Center, a research arm of Consumer Reports' National Testing and Research Center in Yonkers, N.Y. The National Research Center is comprised of highly trained social scientists and conducts more than 200 qualitative and quantitative projects annually, surveying consumers about a wide range of topics. The surveys we conduct on consumer sentiment regarding organic food labeling, which we use to develop our comments to the NOSB, use national probability samples to accurately represent the entire U.S. population.

Like the rest of Consumer Reports, the National Research Center is free of corporate influence and advertising. Surveys are never commissioned or financed by industry. Rather, these surveys are designed by survey scientists to gather unbiased, objective information from consumers.

Material Review - The Importance of OFPA Criteria

According to our 2015 consumer survey, an overwhelming majority (86%) of consumers expect organic foods to be free from artificial ingredients¹, and this expectation is rooted in the organic law and regulations. Consumers should be able to expect that any synthetic and non-organic materials that are used in organic farming and handling have been carefully reviewed to the consistent set of criteria outlined in the Organic Foods Production Act of 1990: harmlessness to human health and the environment, essentiality for organic production, and consistency with organic farming and handling.

Consumers should also be able to expect that organic farmers and handlers are using only synthetic and non-organic materials that meet all criteria in OFPA.

We urge the NOSB to review each material to OFPA criteria and to ensure that all criteria are met. While other considerations may be of interest to some stakeholders, such as whether certain products will need to be reformulated or whether a certain material is useful to some food processors, these considerations are not OFPA criteria.

Livestock Subcommittee

Antibiotic Use in Organic Hatcheries

Eliminating the routine use of antibiotics in healthy food animals is a top priority for Consumer Reports, given the connection between the overuse of antibiotics and the development of antibiotic resistance. While the organic standards prohibit the routine use of antibiotics, there is an exception: the Organic Foods Production Act of 1990 allows for

¹ Consumer Reports National Research Center. 2016. *Natural Food Labels Survey: 2015 Nationally-Representative Phone Survey*. At: http://greenerchoices.org/wp-content/uploads/2016/08/CR_2015_Natural_Food_Labels_Survey.pdf

the use of antibiotics in chicks prior to day two of life because it exempts day-old chicks from organic management.²

This creates inconsistency in the organic standards, and means that the organic label on poultry fails to meet consumer expectations. In our 2015 consumer survey on food labels, 82% of consumers responded that they think federal organic standards should mean no antibiotics or other drugs were used.³

We have repeatedly requested that the NOSB take action on this issue and recommend a clear prohibition on antibiotics at all stages of life for all farm animals used in organic food production. In recent years, major poultry producers, including Perdue and Tyson Foods, have phased out the use of antibiotics in hatcheries (including for conventional production).

We recognize certain OFPA limitations concerning day-old poultry; however, the OFPA provision exempting day-old poultry from organic production standards does not prohibit the application of individual aspects of the organic standards. Instead, the provision merely states that organic standards cannot be required for day-old poultry as a whole. Prohibiting the administration of antibiotics to day-old chicks, or *in ovo*, does not amount to a requirement that these products adhere to organic production standards across the board. Rather, it adds a singular requirement that would satisfy a key purpose of OFPA concerning consumer assurance and organic consistency, as well as other mandatory labeling standards under separate acts.

Therefore, the OFPA exemption for day-old chicks from organic management does not prevent the NOSB from recommending a prohibition on all antibiotic use in organic poultry production.

This could be achieved by recommending the following addition (in bold) to 7 CFR 205.238(c)(1)

(c) The producer of an organic livestock operation must not:

*(1) Sell, label, or represent as organic any animal or edible product derived from any animal treated with antibiotics, any substance that contains a synthetic substance not allowed under §205.603, or any substance that contains a nonsynthetic substance prohibited in §205.604. **The prohibition on antibiotics treatment applies to poultry not under organic management prior to day two of life.***

² 7 U.S.C. § 6509(e)(1).

³ Consumer Reports National Research Center. 2016. *Op cit.*

We strongly urge the NOSB's Livestock Subcommittee to begin work developing a recommendation prohibiting all antibiotic use in organic poultry production. Our full legal analysis on this issue is included in the Appendix.

Crops Subcommittee

Petition: Natamycin

DSM Food Specialties B.V. petitioned to classify natamycin as an allowed nonsynthetic substance in 2016. Natamycin is a polyene macrolide antiinfective, derived from *Streptomyces natalensis*, that is used to control/kill yeasts and filamentous fungi such as *Candida* spp., *Aspergillus* spp., *Cephalosporium* spp., *Fusarium* spp. and *Penicillium* in food. The petitioned uses include “as a fungistat in enclosed mushroom production facilities and for use as a postharvest treatment on food commodities to control fungal diseases.” Natamycin can also be used as a food preservative, such as on the surfaces/rinds of cheeses and sausages or in yogurt.⁴ However, the petitioner has not requested that natamycin be added to section 605 of the National List, and therefore these uses would continue to be prohibited in organic handling. While we agree that natamycin is a nonsynthetic, we urge the NOSB to reject the petition due to potential public health concerns associated with selection for resistance in fungal pathogens. Thus it does not meet the standard of harmlessness to human health in OFPA.

In 2007, the National Organic Standards Board (NOSB) reviewed and rejected a petition for the use of natamycin as a preservative on the grounds that natamycin was a synthetic, noting that “Synthetic materials whose sole purpose is as a preservative are not consistent with organic principles.”⁵ The NOSB finding that natamycin was a synthetic is puzzling since the August 2006 technical report (TR) and the NOP Draft Guidance for Classification of Materials 5033, section 4.6 indicated that natamycin should be classified as a nonsynthetic.⁶

In 2013, the Organic Materials Review Institute (OMRI) evaluated and approved natamycin as a nonsynthetic for use as an organic crop input in accordance with the NOP Draft Guidance for Classification of Materials 5033. However, OMRI has classified

⁴ Raab WP. 1972. Natamycin (Pimaricin): its properties and possibilities in medicine.

⁵ NOSB. 2007. NOSB Committee Recommendation: Natamycin. At: <https://www.ams.usda.gov/sites/default/files/media/Nata%20NOSB%20Committee%20Recommendation.pdf>

⁶

natamycin as an issue Beyond Resolution, based on the fact that “Although OMRI has determined that natamycin is a nonsynthetic material based on the National Organic Program (NOP) Guidance on Classification of Materials (NOP 5033), the NOP has stated that this substance is not allowed under the NOP regulations and has instructed OMRI not to list products containing natamycin. The NOP has acknowledged that interested parties may submit a petition for natamycin’s use in organic production.”⁷ The petition by DSM Food Specialties B.V. also states that based on new information not available to NOP in 2007, natamycin is a nonsynthetic material based on the National Organic Program (NOP) Guidance on Classification of Materials (NOP 5033).

We agree that natamycin should be classified as a nonsynthetic substance. However, we believe that the petition to list natamycin as an allowed nonsynthetic should be rejected on the basis of the potential threat to public health. Although natamycin is used as a food preservative it also has human uses. Natamycin is used in people as a topical treatment of fungal eye, mouth, skin and vaginal infections. Other polyene macrolide antifungals used in human medicine are amphotericin B and nystatin.⁸ Amphotericin B is of particular importance to treat serious life threatening fungal infections--such as vaginal or intestinal *Candida* infections in immunocompromised patients such as the elderly, transplant recipients, or patients with cancer or HIV--since *Candida* has developed resistance to other drugs and is only susceptible to the polyene antifungals. More recently, resistance to amphotericin has been found in *Candida* spp. causing invasive diseases and there is evidence that resistance has developed in *Aspergillus* isolated from patients with blood malignancies.⁹ There is concern that resistance genes for amphotericin B or natamycin could spread via horizontal gene transfer among *Candida* species or between *Candida* and *Aspergillus*.

Use of natamycin as a surface treatment has been shown to be safe, since the estimated dietary exposure to natamycin from such surface treatments is ten times lower than the acceptable daily intake (ADI) as defined by the Joint Food and Agriculture Organization (FAO) and World Health Organization (WHO) Expert Committee on Food Additives (JECFA).¹⁰ However, the ADI derived by JECFA was published in 1968. More recently, more soluble versions of natamycin, particularly natamycin-cyclodextrin inclusion complexes, have been developed for use in production of yogurt, and juices and wines. Such uses of natamycin could result in high exposures of *Candida* in the gut. A

⁷ Organic Materials Research Institute (OMRI). OMRI FAQ. At: <https://www.omri.org/faq>

⁸ Dalhoff AAH and SB Levy. 2015. Does use of the polyene natamycin as a food preservative jeopardise the clinical efficacy of amphotericin B? A word of concern. *International Journal of Antimicrobial Agents*, 45: 564-567. At: [https://www.ijaaonline.com/article/S0924-8579\(15\)00102-8/pdf](https://www.ijaaonline.com/article/S0924-8579(15)00102-8/pdf)

⁹ *Id.*

¹⁰ JECFA. 1964.

paper published in 2015, “Does use of the polyene natamycin as a food preservative jeopardise the clinical efficacy of amphotericin B? A word of concern,” argued that the high exposures associated with natamycin use in yogurt and other beverages could select for spread of resistance to polyene antifungals: “Consumption of food to which natamycin has been added and mixed homogeneously, such as yoghurt, and in particular the addition of cyclodextrin inclusion complexes to beverages and wine generates high faecal natamycin concentrations resulting in high drug exposures of faecal *Candida* spp. Development of natamycin resistance has been observed in *Candida* spp. colonising the intestinal tract of patients following natamycin treatment of fungal infections. Horizontal gene transfer among different *Candida* spp. and within *Aspergillus fumigatus* spreads resistance. Therefore, it cannot be denied that use of natamycin for preservation of yoghurt and beverages may foster development of resistance to polyenes in *Candida* spp.,”¹¹ thereby “hypothetically putting elderly and immunocompromised patients at risk.”

We agree with the Crops Subcommittee’s recommendation to add natamycin to the National List as a prohibited nonsynthetic substance (205.602). Given the potential risk to human health via the development of resistance to natamycin and the spread of those resistance genes among *Candida* and *Aspergillus* species, which could render polyene antifungals such as amphotericin B ineffective for treatment of fungal infections, we urge the NOSB to add natamycin to section 205.602 of the National List. .

Materials Subcommittee

Proposal: Genetic Integrity of Transparency of Seed Grown on Organic Land

A majority of consumers (72%) expect foods labeled “organic” to mean no GMOs were used, according to our 2015 consumer survey.¹² We therefore support approval of the proposal on “Genetic integrity transparency of seed grown on organic land.”

Proposal: Excluded Methods Terminology

At the fall 2017 meeting, we were glad that the NOSB accepted the Materials Subcommittee’s recommendation to include cisgenesis, intragenesis, and agro-infiltration in the terminology for excluded methods and to exempt the techniques of marker-assisted selection and transduction. However, the discussion document used to support those

¹¹ Pg. 564 in Dalhoff and Levy. 2015. *Op cit.*

¹² Consumer Reports National Research Center. 2016. *Op cit.*

recommendations did not include definitions for agro-infiltration, cisgenesis and intragenesis. We recommend that definitions be developed for agro-infiltration, cisgenesis and intragenesis, with proposed definitions below. We support the Materials Subcommittee’s proposal to list “embryo rescue in plants” as “not an excluded method.” As for the proposal to add “transposons, when produced from chemicals, artificial ultraviolet radiation or other synthetic methods” to the table listing excluded methods, we only support adding “transposons, when produced using *in vitro* or other synthetic methods,” to the table listing excluded methods, since use of chemical or ultraviolet radiation should be considered under “induced mutagenesis,” which is still in the table of methods TBD (to be determined).

Agro-infiltration, as the accompanying note in the fall 2016 discussion document’s chart explains, means “in vitro nucleic acids are introduced to plant leaves to be infiltrated into them.” We suggest that this should be the definition for agro-infiltration. Thus, agro-infiltration is clearly an in vitro nucleic acid technique and clearly falls under the definition of “modern biotechnology.”

In order not to create any confusion, we urge the Materials Subcommittee to define the terms cisgenesis and intragenesis. As we noted in our previous comments, cisgenesis refers to “the genetic modification of a recipient plant with a natural gene from a crossable—sexually compatible—plant. Such a gene includes its introns and is flanked by its native promoter and terminator in the normal-sense orientation.”¹³ We suggest this should be the definition for “cisgenesis.”

Intragenesis also involves the genetic engineering (or genetic modification) of a recipient plant with hybrid genes from a crossable species. Unlike cisgenesis, with intragenesis, the regulatory components of the gene (e.g., the promoter and the terminator region) do not need to come from the same species; they can come from a crossable species, hence their being called a hybrid gene.¹⁴ Thus, a definition for “intragenesis” could be, “full or partial coding DNA sequences of genes originating from the sexually compatible gene pool of the recipient plant, and arranged in sense or antisense orientation. In addition, the promoter, spacer and terminator may originate from sexually compatible gene pool of the recipient plant.”¹⁵ DNA is a double helix. One strand of the DNA, called the coding, or sense, strand, runs in a 5’ to 3’ direction and codes for the gene of interest. It is normally the sense strand of DNA that is transcribed into mRNA,

¹³ Schouten HJ, Krens FA and E Jacobsen. 2006. Cisgenic plants are similar to traditionally bred plants. *EMBO Reports*, 7(8): 750-753. At: www.ncbi.nlm.nih.gov/pmc/articles/PMC1525145/pdf/7400769.pdf

¹⁴ See slide 11 in www.slideshare.net/HudaNazeer/transgenesis-intragenesis-cisgenesis

¹⁵ Holme IB, Wendt T and PB Holm. 2013. Intragenesis and cisgenesis as alternatives to transgenic crop development. *Plant Biotechnology Journal*, 11: 395-407. At: <https://onlinelibrary.wiley.com/doi/epdf/10.1111/pbi.12055>

rRNA or tRNA. The complementary strand of DNA is called the noncoding, or antisense strand, and runs in the 3' to 5' direction. Consequently, you could take a coding strand gene, turn it around and, using genetic engineering techniques, insert it back into the coding strand, but now the gene will be in the antisense orientation. The gene product that is produced with this antisense orientation will turn off the gene product produced by the sense orientation. For example, the FLAVR SAVR tomato took the gene responsible for the enzyme that breaks down the cell wall (polygalacturonase) and inserted into the tomato in the antisense direction, with the result that the levels of polygalacturonase were dramatically reduced so the tomato didn't soften.

Transposons, also known as “jumping genes,” are mobile genetic elements that have been used to genetically engineer plants¹⁶ and animals.¹⁷ Transposons used in genetic engineering are developed in a lab using *in vitro* nucleic acid techniques and then introduced into plants or animals. These uses clearly constitute an excluded method since *in vitro* nucleic acid techniques are part of the definition of “modern biotechnology” or genetic engineering.

Transposons also occur naturally and are responsible for mutations when moving around in a genome.¹⁸ Increased movement of naturally occurring transposons within a genome, which results in higher mutation rates, can be induced by various forms of stress, such as via environmental stress, e.g., heat, cold or drought, or via stresses caused by chemicals or irradiation. At this time, we think that only transposons developed via use of *in vitro* nucleic acid techniques should be determined to be an excluded method. We believe that the determination of whether transposons induced via chemicals or irradiation are classified as an excluded method should be considered under the method of “induced mutagenesis”—which is listed as a method TBD (to be determined), for which more research and discussion is needed—since chemical/radiation-induced mutations via naturally occurring transposons are just a subset of mutations caused by chemicals or irradiation. Use of chemicals or irradiation can lead to mutations via chromosome breaks, insertions, deletions and chromosome rearrangement, in addition to mutations caused by movement of transposons. In addition, we do not know if the mutation rates resulting from greater movement of naturally occurring transposons due to

¹⁶ Contreras B, Vives C, Castells R and JM Casacuberta. 2015. Chapter 6. The impact of transposable elements in the evolution of plant genomes: From selfish elements to key players. Pp. 93-105 in Pontarotti P (ed), *Evolutionary Biology: Biodiversification from Genotype to Phenotype*. Springer International Publishing, Switzerland. At:

https://www.researchgate.net/publication/299867092_The_Impact_of_Transposable_Elements_in_the_Evolution_of_Plant_Genomes_From_Selfish_Elements_to_Key_Players

¹⁷ Muñoz-López M and JL García-Pérez. 2010. DNA transposons: Nature and application in genomics. *Current Genomics*, 11: 115-128. At:

<https://www.ohio.edu/plantbio/staff/showalte/MCB%20720/a%20Transposon%20Paper%20113016.pdf>

¹⁸ Contreras et al. 2015 *Op cit.*; Muñoz-López M and JL García-Pérez. 2010. *Op cit.*

chemical/irradiation are greater than the mutation rate resulting from environmental stresses, which are not considered to be an excluded method. So, we feel it is best to put off the decision as to whether the use of chemicals or irradiation to increase rates of mutations via increased rates of naturally occurring transposon movement should be an excluded method until a decision has been made about “induced mutagenesis.”

Transposons can also be used to create animal vaccines. While vaccines, whether genetically engineered (GE) or not, are presently are not prohibited in the organic program, due to being listed under 205.603--synthetic substances allowed for use in organic production--vaccines have come up for sunset review. At present, we believe that NOSB should work with USDA and industry to determine whether specific vaccines engineered using transposons may be used if it can be shown that non-GE versions are not available.

In summary, we support the Materials/GMO Subcommittee’s proposal to list “embryo rescue in plants” as “not an excluded method.” As for the proposal to add “transposons, when produced from chemicals, artificial ultraviolet radiation or other synthetic methods” to the table listing excluded methods, we only support adding “transposons, when produced using *in vitro* or other synthetic methods,” to the table listing excluded methods, since use of chemical or ultraviolet radiation should be considered under “induced mutagenesis,” which is still in the table of methods TBD (to be determined). We also urge the subcommittee proposal to develop definitions for cisgenesis, intragenesis, and agro-infiltration.

Handling Subcommittee

Proposal: Silver dihydrogen citrate

One major concern with silver dihydrogen citrate, proposed for use as a sanitizer to kill bacteria, is that it could be an engineered nanomaterial. The NOSB, noting universal public opposition to the use of nanotechnology and engineered nanomaterials in organic production, voted to exclude engineered nanomaterials in 2010.¹⁹ NOP did not

¹⁹ NOSB. 2010. Guidance Document -- Engineered Nanomaterials in Organic Production, Processing and Packaging. At: <https://www.ams.usda.gov/sites/default/files/media/NOP%20Materials%20Final%20Rec%20Engineered%20Nonomaterials.pdf>

adopt the recommendation, but said that petitions for nanomaterials would be treated as any other petitions.²⁰

The Handling Subcommittee has recommended that the proposal for silver dihydrogen citrate be approved with the recommended annotation, “limited to particle sizes greater than 300 nm,” so that other products that contain nanosilver would not be allowed if this petition is approved. The petitioner maintains that silver dihydrogen citrate is not nanosilver, but is ionic silver. However, it should be pointed out that the largest silver ions are 0.129 nm in size²¹ and so are smaller than 300 nm.

In addition, there are problems with ionic silver *per se* that should result in the denial of this position. The most important problem with ionic silver is that it could exacerbate the spread of antimicrobial resistance. The Centers for Disease Control and Prevention (CDC) has called antimicrobial resistance “one of the world’s most pressing public health problems.”²²

Silver is used in medicine, particularly for burn and wound therapies. Not only does silver have antimicrobial properties, evidence from animal models show that silver may also improve wound healing by reducing local inflammation and facilitation of wound healing. Indeed, FDA has approved marketing clearance for many silver-impregnated wound dressings and topical agents which are readily available.²³ Any development of antimicrobial resistance to silver could significantly impact the use of silver dressings in health care, so it is important to avoid unnecessary use of silver that could lead to resistance.

The technical review (TR) for silver dihydrogen citrate states that bacterial resistance to the petitioned substance has not been reported. However, a number of studies have been published in recent years that demonstrate that such resistance to ionic silver has been reported. A paper published in 2005 found that two silver-resistant strains of *Enterobacter cloacae* from infected teeth containing dental restorations and both strains were also resistant to ampicillin, erythromycin, and clindamycin.²⁴ Indeed,

²⁰ NOP Policy Memorandum 15-2, “Nanotechnology” March 24, 2015. At:

<https://www.ams.usda.gov/sites/default/files/media/NOP-PM-15-2-Nanotechnology.pdf>

²¹ <https://www.saylor.org/site/wp-content/uploads/2011/06/Ionic-Radius.pdf>

²² CDC. 2018. “Get Smart: Know When Antibiotics Work. At: <http://www.cdc.gov/getsmart/antibiotic-use/fast-facts.html>

²³ Finley PJ, Norton R, Austin C, Mitchell A, Zank S and P Durham. 2015. Unprecedented silver resistance in clinically isolated *Enterobacteriaceae*: Major implications for burn and wound management, 59(8): 4734-4741. At: <https://aac.asm.org/content/aac/59/8/4734.full.pdf>

²⁴ Davis IJ, Richards H and P Mullany. 2005. Isolation of silver-and antibiotic-resistant *Enterobacter cloacae* from teeth. *Oral Microbiology and Immunology*, 20(3): 191-194. At: <https://www.ncbi.nlm.nih.gov/pubmed/15836522>

resistance to silver and antibiotics are frequently found together. In fact, the initial molecular basis for silver resistance is plasmid pMG101, isolated from *Salmonella* species, which contains resistance to silver, other heavy metals, and multiple antibiotics.²⁵ However, although many silver resistance genes have been found in numerous bacteria, there has been very little evidence that presence of these silver resistance genes has led to clinically significant phenotypic expression. For example, an investigation of silver resistance in MRSA (methicillin-resistant *S. aureus*) isolated from humans and animals showed only 3 isolates out of 41 samples tested that were positive for various silver resistance genes. However, all three strains with silver resistance genes remained sensitive to low silver concentrations.²⁶

More recently, a paper published in 2015 found the first strains of clinical bacteria expressing silver resistance at a level that could significantly impact wound care and use of silver-based dressings.²⁷ The study screened 859 clinical isolates of 60 different species, with the majority of isolates belonging to *Staphylococcus*, *Escherichia*, *Pseudomonas*, *Klebsiella*, *Enterococcus*, *Enterobacter* and *Candida* genera. Of these isolates, 31 contained one or more silver resistance genes. Despite the presence of these resistance genes, most of the bacteria displayed little or no resistance to ionic silver. However, two isolates—*Klebsiella pneumonia* and *Enterobacter cloacae*—were capable of robust growth at exceedingly high silver concentrations. These two isolates showed darkening of the bacteria's pigment after exposure to high concentrations of silver. The darkening was the result of the presence of silver nanoparticles embedded in the extracellular portion of both isolates. The study noted that this “finding suggested that the isolates may neutralize ionic silver via reduction to elemental silver. Antimicrobial testing revealed both organisms to be completely resistant to many commercially available silver-impregnated burn and wound dressings. Taken together, these findings provide the first evidence of clinical bacteria capable of expressing silver resistance at levels that could significantly impact wound management.”²⁸ Of the nine silver-impregnated wound dressings tested, two—Maxorg-Ag and Mepilex-Ag—contained ionic silver and showed no reduction in bacteria levels after exposure to very high silver concentration.

The Finley et al. study clearly shows that ionic silver can select for resistance in clinically significant bacteria that could adversely impact wound management.

²⁵ Gupta A, Matsui K, Lo JF, Silver S. 1999. Molecular basis for resistance to silver cations in *Salmonella*. *Nature Medicine* 5:183–188. <http://dx.doi.org/10.1038/5545>.

²⁶ Loh JV, Percival SL, Woods EJ, Williams MJ and CA Cochrane. 2009. Silver resistance in MRSA isolated from wound and nasal sources in humans and animals. *International Wound Journal*, 6(1):32–38. At: <https://onlinelibrary.wiley.com/doi/pdf/10.1111/j.1742-481X.2008.00563.x>.

²⁷ Finley et al., 2015. *Op cit*.

²⁸ Pg. 4734 in *Id*

Consequently, it is important to avoid promoting unnecessary uses of silver that could increase the spread of silver resistance. Use of silver dihydrogen for use on food is such an unnecessary use of silver.

Finally, the petitioner has not argued in the petition justification that silver dihydrogen citrate is essential to organic production and handling. It has presented arguments of the benefits of the material –arguments that should be considered in a comprehensive review of cleansers, disinfectants, and sanitizers. Only through such a review –which would establish the need for such materials in organic production and handling, as well as the relative benefits of available materials— can the essentiality for a petitioned sanitizer be established. Information in the petition and technical review is not sufficient.

In conclusion, we oppose the petition for silver dihydrogen citrate. Although the proposed annotation does not allow nanosilver, silver dihydrogen citrate poses a risk of increasing the resistance to antibiotics and silver-based medications used in wound management. The technical review has not shown that silver dihydrogen citrate is essential to organic production and handling. For these reasons, we urge the NOSB to reject the petition for silver dihydrogen citrate.

Sunset review: flavors

At its meeting in the fall of 2015, the NOSB voted to change the annotation for “flavors” to: “Flavors, non-synthetic flavors may be used when organic flavors are not commercially available. All flavors must be derived from organic or non-synthetic sources only and must not be produced using synthetic solvents and carrier systems or any artificial preservative.” This recommendation has not been adopted by the NOP. We support relisting flavors only if the NOSB includes this annotation in its recommendation, and reiterates that the NOP should adopt the revised annotation.

Sunset review: Fructooligosaccharides

Fructooligosaccharides are highly processed isolates of sugars that are derived from plants such as chicory, sunchokes, agave, or from sugar extracted from sugar cane or sugar beet and subsequently fermented. This food additive fails to meet the criteria in the Organic Foods Production Act for inclusion on the National List as an allowed non-organic ingredient because it is not necessary to the production or handling of any organic product.

The ingredient is added to processed foods to allow the manufacturer to make certain marketing claims related to the perceived health benefits of highly isolated fibers and sugars. Sometimes the line between what is considered a necessary material in organic processing and what is merely useful or convenient is not clear; however, in the

case of fructooligosaccharides, it is abundantly clear that it is entirely possible to make yogurt, frozen yogurt, milk and bread without it. In fact, some manufacturers that used to add fructooligosaccharides to their organic products no longer appear to do so, likely because the fad of adding it for its perceived health benefits has passed.

Even during the last sunset cycle, the subcommittee noted that it had received “limited feedback from users.” During the 2010 comment period, some manufacturers commented that they used fructooligosaccharides, but gave no reasons for why it should be relisted. We believe that fructooligosaccharides have never been essential to producing organic foods, and should never have been added to the National List as an allowed non-organic ingredient.

We urge the NOSB to remove fructooligosaccharides from 205.606 of the National List because this non-organic, highly processed food additive has never been necessary to the production of organic foods, and therefore fails to meet the essentiality criterion.

Sunset review: gums (arabic, guar, locust bean, and carob bean)

We do not oppose the relisting of gums, especially since these gums are alternatives for the use of carrageenan, a gum that raises human health concerns.

Certified organic foods should consist of certified organic ingredients, and non-organic, nonsynthetic or synthetic ingredients should be allowed only when organic alternatives are not available. Organic versions of the agricultural gums are available, and therefore these gums should be listed separately on the National List. Currently, they appear as a group: “gums: arabic, carob bean, guar, locust bean.” The TER notes that carob bean gum and locust bean gum are two different names for the same gum; therefore, these two listings should be combined. When adequate commercial availability of organic alternatives of one or more of these three gums is achieved, these should be removed from the National List and organic versions should be required. To facilitate this process, we urge the NOSB to list each gum separately.

Thank you for considering our comments. We encourage the Board to reach out to us if questions arise; we are happy to provide more information and background materials on any of the topics in this comment.