ConsumerReports®

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National Organic Standards Board
USDA-AMS-NOP
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Washington, D.C. 20250

Submitted via www.regulations.gov.

Comments of Consumer Reports to the National Organic Standards Board on the Spring 2016 Meeting
Docket No. AMS-NOP-15-0085

Consumer Reports welcomes the opportunity to comment on proposals and discussion documents posted for the Spring 2016 meeting of the National Organic Standards Board (NOSB) in Washington, D.C..

Since its founding in 1936 as an independent, non-profit organization, Consumer Reports has empowered consumers with the knowledge they need to make better and more informed choices—and has battled in the public and private sectors for safer products and fair market practices. Consumer Reports serves consumers through unbiased product testing and ratings, research, journalism, public education, and advocacy. Consumer Reports has over 8 million subscribers to its magazine, website and other publications.

Consumer Reports' Food Safety and Sustainability Center was launched in 2012 to fight for sweeping, systemic change and address the root causes of problems plaguing the food system. The Center focuses on issues including foodborne illness and antibiotic resistance; pesticide use; heavy metals (mercury, lead, arsenic); truth and transparency in labeling; and promoting more sustainable agricultural practices that advance the marketplace, such as improved animal welfare, organic farming, and fair trade. At the core of the Center's work is the principle that there is a clear intersection between how food is produced and the impact on public health.

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Protecting the Integrity of the Organic Label

The value of the organic label lies in the strength of the organic law and regulations, which promise consumers a consistent standard for organically produced foods and create a meaningful process with strict limits for determining what can and cannot be used in organic food production.

A majority of consumers care about avoiding artificial ingredients in the foods they buy; our 2015 nationally representative consumer survey found that this is an important objective for 79% of consumers. Consumers also overwhelmingly expect organic foods to be free from artificial ingredients and colors: 86% of consumers polled in our 2015 survey think that the organic label should mean no artificial ingredients or colors. Please see results from our 2015 and 2016 consumer surveys in the appendix.

Given that consumers expect organic foods to be free from synthetic ingredients, and that this expectation is rooted in the organic law and regulations, they have every right to expect that synthetic and non-organic materials that are used in organic farming and handling have been carefully reviewed to a consistent set of criteria: harmlessness to human health and the environment, essentiality for organic production, and consistency with organic farming and handling. Consumers also have a right to expect that organic farmers and handlers are using only synthetic and non-organic materials that meet **all** criteria in the law.

In our 2016 consumer survey, we specifically asked consumers about one of these criteria: essentiality. Seventy percent of consumers responded that the USDA should not permit the use of non-organic ingredients in organic food production if the ingredient is not deemed essential.

We urge the NOSB to review every material -- both petitions and sunset reviews -- to Organic Foods Production Act (OFPA) criteria and ensure that all criteria are met. While other considerations may be of interest to some stakeholders, such as whether certain products will need be reformulated, these considerations are not OFPA criteria.

We also wish to voice our continued concern with the National Organic Program's (NOP) changes to the sunset review process, which undermine organic integrity and consumers' expectations for organic. We are concerned that the NOP has made it easier to maintain the use of non-organic, otherwise-prohibited materials in organic production and to minimize the incentive to create organic alternatives. This is counter to consumer expectations. As we have in the past, we continue to urge all of the subcommittees and NOSB as a whole to demand that the NOP's Sunset Notice be subjected to notice and comment.

Materials Subcommittee

Proposal and Discussion Document: Excluded Methods Terminology

We welcome the opportunity to comment on the NOSB's proposal and discussion document on Excluded Method Terminology. We fully agree with NOSB that the terminology for "excluded methods" needs to be updated to deal with new methods to genetically engineer (or 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."

We also believe that the National Organic Program should have clear and consistent standards to ensure there will be no use of present and future genetic engineering technologies so that all GMOs will continue to be prohibited for use in organic agriculture.

At present, the methods listed in the rule (7 CFR 205.2; Terms Defined) are not adequate. In terms of the proposal put forward by the Materials Subcommittee, for the reasons mentioned below we will make a few recommendations on modifications on the definitions proposed, and also feel that the Principles and Criteria section should be returned to the subcommittee for further work to make it clear all engineered organisms, be they plants, animals, arthropods, bacteria or fungi should be excluded from organic agriculture.

In addition, for the Terminology chart, we believe the subcommittee should consider convening a small groups of scientists and all affected stakeholders (e.g., industry, consumers, farmers and organic seed breeders) to more fully discuss the methods on the chart and come back with a further proposal at the fall NOSB meeting.

Definitions

Modern Biotechnology:

We strongly feel that NOSB should use the definition of "modern biotechnology" referenced by Codex Alimentarius as its main definition of excluded methods.

We urge NOSB to reference Codex Alimentarius as the source for this definition for a couple of reasons. First, the U.S. is a member organization of Codex Alimentarius, but is not a member of, or party to, the Convention on Biological Diversity and so does not recognize the CPB. Codex Alimentarius has also produced a document, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CAC/GL 1999/2013), which would be

relevant here and that would also use the definition of modern biotechnology in place of genetic engineering/genetic modification. We believe that the definition of "modern biotechnology" is broad enough to encompass virtually all the newer genetic engineering techniques such as RNAi, gene editing technologies (e.g., CRISPR Cas9, TALEN, zinc-fingered nucleases, meganucleases), use of gene drives, oligonucleotide directed mutagenesis, reverse breeding, RNA-dependent DNA methylation, cisgenesis, transgenesis, grafting involving non-GE stock grafted onto GE rootstock (or vice versa), etc.

In addition, all Codex standards, guidelines, etc. are referenced by the World Trade Organization and are considered to be "trade legal," so using this global definition in organic would help ensure that U.S. organic products are not rejected from a foreign country. Second, reference to the Cartagena Protocol could create some ambiguity since in addition to "modern biotechnology," CPB also defines a "living modified organism" as "any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology." Since an LMO is a synonym for GMO, this could create problems since an organism that is produced via "modern biotechnology," but does not contain "a novel combination of genetic material" would fall outside of the definition of LMO/GMO, and so there could be debate about what constitutes a "novel combination of genetic material." If you use techniques of modern biotechnology to insert a gene that can already be found in the same species, that could fall outside of the definition of LMO/GMO as could some organisms that are created by synthetic biology. Codex Alimentarius does not have a definition of LMO/GMO and simply refers to a product of "modern biotechnology." Third, we note that the Food and Drug Administration, most recently, in its "Draft Guidance for Industry: Voluntary Labeling Indicating Whether Food Has or Has Not Been Derived From Genetically Engineered Atlantic Salmon," has stated that the terms "bioengineered," "bioengineering" and "genetic engineering" all describe the use of "modern biotechnology." Thus, for these reasons, we think the Codex definition of "modern biotechnology" found in the Principles for Risk Analysis of Foods Derived from Modern Biotechnology (CAC/GL 44, 2003/2011), should be the reference for definition of "modern biotechnology."

Although we think that the definition of "modern biotechnology" will encompass products produced via synthetic biology, we suggest moving the definition of "synthetic biology" to appear right after "modern biotechnology" in order to be absolutely clear that it does.

Genetic engineering:
Given that we believe that "modern biotechnology" should be the major term used, we suggest changing the definition to "the use of modern biotechnology to alter or recombine the genetic material of plants, animals (including invertebrates), micro-organisms, cells and other biological units."

Genetically Modified Organism:

We suggest changing this definition to "Plant, animal, micro-organism, cell or other biological units developed using modern biotechnology." This term will also apply to the products and derivatives produced using modern biotechnology.

Non-GMO:
We are fine with this definition as stands.

Principles and Criteria

We agree with much of what is written in the Principles and Criteria section, but the section should be reworked to include more up to date discussion of the newer techniques of modern biotechnology, including synthetic biology. Thus, an independent committee of scientists and affected stakeholders should put together a new proposal for discussion this fall.

In addition, we believe the beginning of Point 1.11 of the Principles of Organic Production and Handling in the Policy and Procedures Manual, should be modified to read "Genetic engineering (aka modern biotechnology) is a synthetic process …" so that it is clear that it is not just recombinant DNA technology that is referred to by "genetic engineering." Although we prefer the term "modern biotechnology," we believe that the more recognizable terms "genetic engineering" or "genetic modification" should be used as synonyms for modern biotechnology.

We agree with the four principles laid down by IFOAM as an appropriate guidance for developing a position on technologies used to create GMOs. That said, we urge refinements to the criteria. The criteria listed seem to be restricted primarily to plants, while the techniques of modern biotechnology can be used to modify all organisms, be they plants, animals (including invertebrates), micro-organisms, fungi, or others. The first bullet point talks of *in vitro* nucleic acid techniques being an invasion into the plant genome. In fact, *in vitro* nucleic acid techniques can be considered an invasion into the genome of any organism, not just plants. The second bullet point just refers to plants as it talks about genetic use restriction technologies, such as Terminator technology to prevent seed germination. Animals and fish can be altered in such ways so as to render them sterile, and this issue should be discussed. Thus, the use of pressure can induce triploidy in fish. We would question: should this be permitted? What about the induction of polyploidy in plants using chemicals such as colchicine? Consequently, this criteria section should be reworked by the independent committee mentioned above.

Process and Product

The "Process and Product" section should be reworked as well, for several reasons, and more research needs to be done before it is finalized and a final recommendation is sent to the NOP.

While the terminology chart is useful, we think it is clear that virtually all techniques of modern biotechnology are synthetic and therefore should be excluded from use in organic agriculture. In terms of the technologies on the chart, we have the following comments. We agree that marker assisted breeding should not be an excluded method. However, we believe that the following technologies should be switched from *TBD* to excluded, since they would be covered under the Codex definition of "modern biotechnology" since they all include molecular techniques: protoplast fusion, cisgenesis, intragenesis, and transposons.

The following techniques need a broader discussion in the organic community:

Transduction. Bacteriophages can be and have been used in the control of bacteria, and they include transfer of bacteria and/or viral genetic material by transduction. If the bacteriophages occur naturally, they should be allowed. If the bacteriophage has been genetically engineered, then its use should not be allowed in organic agriculture.

Cell fusion within the plant family. This method is excluded from the definition of "modern biotechnology," as so it would appear to be allowed. However, the original definition of excluded methods mentioned in 7 CFR 205.2; "Terms Defined," includes the term "cell fusion," although that section also states that these "methods don't include the use of traditional breeding." Hundreds of varieties of cruciferous crops have been developed using cell fusion, since it can help in making hybrids by more readily spreading cytoplasmic male sterility, and so it has been a part of "traditional breeding." Although the National Organic Program put out a policy statement in 2013 saying that some forms of cell fusion would be permitted in organic,[1] there is disagreement from within the organic community, such as from the Organic Seed Trade and Growers Association, about whether this should be a permitted technology. There should be more discussion.

Embryo rescue in plants, agro-infiltration, and *doubled-haploid technology*. These three methods have been a part of "traditional breeding" for decades, even before the advent of modern biotechnology. As such, they would appear to be allowed in organic agriculture. However, there are a number of organic groups, such as IFOAM, that do not feel that these techniques are consistent with the principles of organic agriculture as laid out by IFOAM. Thus, these techniques do need to be considered further.

Induced mutagenesis. Historically, radiation breeding and chemical mutagenesis have been permitted in organic agriculture, but there are groups that believe these techniques should not be allowed. This does raise tricky issues if all induced mutagenic techniques are banned in organic. For example, the ruby red grapefruit was produced via radiation breeding. Does that mean that there can no longer be organic ruby red grapefruits? The use of radiation breeding and chemical

[1] McEvoy. 2013. Policy Memorandum: Cell Fusion Techniques Used in Seed Production. At: https://www.ams.usda.gov/sites/default/files/media/NOP-PM-13-1-CellFusion.pdf

mutagenesis should be further discussed since they do appear to contradict the principles of organic as laid down by IFOAM. That said, it is clear that there are newer molecular techniques that also induce mutations, such as oligonucleotide directed mutagenesis or the use of various gene editing techniques, and these should be clearly excluded.

Livestock Subcommittee

Organic Aquaculture Standards

Though not on the agenda for this meeting, we asked consumers in our 2016 survey about standards for organic aquaculture. The results show that consumers expect organic aquaculture standards to require 100% organic feed, prohibit antibiotics and other drugs, prohibit added colors to the feed or fish, and prohibit open net fish pens. Consumers who typically buy organic foods are even more interested than the average consumer in these standards, with nearly three-quarters of consumers who typically buy organic foods opposing open net fish farms.

Should federal standards for fish labeled "organic" require any of the following:

Requirement	All Respondents	Respondents who typically buy "organic" foods
100% organic feed	87%	93%
No antibiotics or other drugs used	82%	88%
No added colors to the feed or fish	80%	87%
No open net fish farms, which allow for the exchange of materials such as waste, chemicals and small wild fish	68%	73%
None of these	4%	2%
No opinion	1%	0%
Don't know	1%	0%

Additional Comments: Poultry Genetics

We are pleased to see that the NOP has released a proposed rule on "Organic Livestock and Poultry Practices" to address animal welfare on organic farms. One issue that is missing from the proposed rule is poultry genetics.

In our Spring 2015 comment to the NOSB, we requested that the NOSB add this topic to its workplan, to develop a recommendation on poultry genetics. We believe there is a need in the organic standards for a requirement preventing the use of poultry breeds and strains that have been selected for rapid growth, which comes at the expense of bird health and welfare.

Poultry breeding programs have focused on achieving rapid growth and large muscles, largely ignoring health problems that arise from such rapid growth. For example, chickens often suffer from leg deformities and lameness due to their rapid growth, and their legs can break or tendons can rupture due to the weight of their breast muscle.

Rapid weight gain also leads to problems with internal organs, especially the heart and lungs, which cannot distribute enough oxygen throughout the enlarged body's muscles. This condition, called ascites, is the leading cause of mortality as the birds reach market weight. Fast-growing birds also often suffer from acute heart failure and Sudden Death Syndrome. These strains can be used in organic production.

In the European Union, organic standards require a minimum age at slaughter to prevent the use of rapidly growing strains. Label programs in the U.S., including Animal Welfare Approved and Demeter Biodynamic, have standards that either set a minimum age at slaughter or prohibit the use of fast-growing broiler strains.

We continue to urge the Livestock Subcommittee to add this topic to its workplan.

Additional Comments: Antibiotics in organic poultry production

Consumers expect organic foods to be produced without antibiotics. Our 2015 national survey shows that 79% of consumers believe that the organic label should mean that antibiotics are only used to treat sick animals and 72% think that no antibiotics should ever be used. Currently, antibiotics can be administered in the egg and the first day of life to poultry that will be raised and sold as "organic."

In December 2013 and again in June 2015, we wrote to Secretary Vilsack requesting that the agency address this inconsistency in the meaning of the organic label. Secretary Vilsack responded in August 2015 that the NOP will be requesting that the NOSB provide a recommendation on management practices for day-old chicks. As we did in our Fall 2015

comment, we continue to urge the NOSB Livestock Subcommittee to place this issue on its workplan.

"Organic" is widely marketed to consumers as meaning "no antibiotics." Yet while the standards expressly prohibit any animal treated with antibiotics to be sold, labeled or represented as "organic" (see 7 C.F.R. § 205.238(c)(1)), the organic law (section 6509(e)(1)) and standards (7 C.F.R. § 205.236(a)(1)) exempt day-old chicks from organic management.

One of the most common antibiotics administered to day-old chicks in conventional hatcheries for the prevention of disease is gentamicin. Gentamicin is classified by the World Health Organization as "critically important" for human medicine, as it is the sole therapy or one of few alternatives to treat serious human disease.

The emergence of antimicrobial resistance is a serious and urgent public health concern. In 2013, the Centers for Disease Control and Prevention released a report that notes that 23,000 human deaths could be attributed to the development of antibiotic resistance from overuse of antibiotics, including in agricultural settings.

Major conventional poultry producers, including Perdue Foods and Tyson Foods, announced in 2014 that they are ending the practice of administering antibiotics in hatcheries.

The use of antibiotics such as gentamicin to prevent disease in day-old chicks is disconcerting in any segment of agriculture, but especially when it continues to be permitted for chicks that are raised under organic management after the first day of their lives and eventually sold as "organic."

We urge the NOSB to add this issue to its workplan and begin working on a recommendation to prohibit antibiotics in organic poultry production, at all stages of production.

Policy Development Subcommittee

Discussion Document: Sunset Timeline Reorganization

We agree with the Policy Development Subcommittee that the current schedule for sunset review, with 187 materials in one year and 27 materials over four years, is an inefficient use of resources and board time. We support the proposal to evenly distribute the materials over time.

We think that the redistribution also gives the Board an opportunity to organize the materials in a way that will further optimize Board resources and time. We support grouping similar materials for review, and support Option B. We also see benefits to Option's C proposal of grouping materials regardless of which National List section they are listed on. We would support a reorganization that combines Option B and Option C, if this would be feasible. This means grouping similar materials together, and reviewing them across lists.

We support the proposal that materials that are reviewed on a shorter timeline than 5 years and are voted for removal would still be removed at their original sunset date.

Handling Subcommittee

Sunset Review: Carrageenan

We oppose the relisting of carrageenan. Carrageenan fails to meet several criteria for inclusion on the National List as an allowed material.

We urged the NOSB to remove carrageenan from the National List when it was reviewed in 2012, as did many other groups, including the National Organic Coalition.

Human health

Consumers expect organic foods to contain only ingredients that are safe for human health. This expectation is rooted in the law: OFPA requires that prohibited materials may be added to the National List for a five-year period only if the use of such substances would not be harmful to human health or the environment.

We are concerned with the safety of carrageenan. Research points to undegraded carrageenan (the type used in foods) causing inflammation.[2] Laboratory research in animals has shown

[2] Borthakur, A., Bhattacharyya, S., et al. (2007) Carrageenan induces interleukin-8 production through distinct Bcl10 pathway in normal human colonic epithelial cells. American Journal of Physiology, Gastrointestinal and Liver Physiology 292(3): G829-38.

Bhattacharyya, S., Dudeja, P.K. et al. (2008) Carrageenan-induced NFkappaB activation depends on distinct pathways mediated by reactive oxygen species and Hsp27 or by Bcl10. *Biochimica and Biophysica Acta* 1780(7-8): 973-82.

Bhattacharyya, S., Borthakur, A. et al. (2010) B-call CLL/lymphoma 10 (BCL10) is required for NF-kappaB production by both canonical and noncanonical pathways and for NF-kappaB-inducing kinase (NIK) phosphorylation. *Journal of Biological Chemistry* 285: 522-30.

ulcerative colitis-like disease and intestinal lesions and ulcerations in some animals.[3] Additional studies in animals have shown carrageenan may act as a promoter of colon tumors.[4]

Research, including industry-sponsored research, suggests that consuming foods with carrageenan exposes consumers to degraded carrageenan.[5] Since degraded carrageenan is listed as possibly carcinogenic to humans (group 2B) by the World Health Organization's International Agency for Research on Cancer (IARC),[6] the levels of degraded carrageenan found in various studies raise safety concerns. More research is necessary to determine the extent of degraded carrageenan in the food supply.

Borthakur, A., Bhattacharyya, S. et al. (2012) Prolongation of carrageenan-induced inflammation in human colonic epithelial cells by activation of an NK-kappaB-BCL10 loop. *Biochimica and Biophysica Acta* 1822(8): 1300-7.

[3] Watt, J. and Marcus, R. (1969) Ulcerative colitis in the guinea-pig caused by seaweed extract. *Journal of Pharmacy and Pharmacology* 21: 187S-188S.

Grasso, P., Sharratt, M. et al. (1973) Studies on carrageenan and large-bowel ulceration in mammals. *Food and Cosmetics Toxicology* 11:555-564.

Engster, M. and Abraham, R. (1976) Cecal response to different molecular weights and types of carrageenan in the guinea pig. *Toxicology and Applied Pharmacology* 38: 265-282.

Corpet, DE, Tache, S. et al (1997) Carrageenan given as a jelly does not initiate, but promotes the growth of aberrant crypt foci in the rat colon. *Cancer Letters* 114:53-55.

[4] Watanabe, K., Reddy, B.S. et al. (1978) Effect of dietary undegraded carrageenan on colon carcinogenesis in F344 rats treated with azoxymethane or methylnitrosourea. *Cancer Research* 38:4427-4430.

Arakawe, S. Okumua, M. et al (1986) Enhancing effect of carrageenan on the induction of rat colonic tumors by 1,2-dimethylhydrazine and its relation to B-glucuronidase activities in feces and other tissues. *Journal of Nutritional Science and Vitaminology* 32:481-485.

[5] Marinalg International, "Status Report on the work of Marinalg International to measure the molecular weight distribution of carrageenan and PES in order to meet the EU specification: less than 5% below 50,000 daltons."

Capron I, Yvon M and Muller G (1996) In-vitro gastric stability of carrageenan. Food Hydrocolloids 10(2): 239-244

Ekström, L.G. (1985) Molecular-weight-distribution and the behaviour of kappa-carrageenan on hydrolysis. Part II. Carbohydrate Research 135: 283-289

Ekström L.G. and Kuivinen J (1983) Molecular weight distribution and hydrolysis behaviour of carrageenans. Carbohydrate Research 116: 89-94

[6] International Agency for Research on Cancer (IARC), Agents Classified by the IARC Monographs, Volumes 1-110. http://monographs.iarc.fr/ENG/Classification/ClassificationsGroupOrder.pdf

Recent research suggests that carrageenan may also contribute to insulin resistance and to the development of Type 2 diabetes.[7] Additional research on this topic is currently underway by two groups of researchers, one at the University of Illinois at Chicago and the other at the University of Tuebingen in Germany.[8]

The organic law allows for the five-year use of prohibited substances only if the use of the substance would not be harmful to human health. In the case of carrageenan, a substantial body of scientific literature points to potential harm. We urge the NOSB to use the Precautionary Principle – if a substance could be harmful, the NOSB should err on the side of caution and protect the safety and health of consumers. The burden of proof should not fall on consumers, nor should the burden of knowing about this literature.

Essentiality

As we have noted repeatedly in past comments and in the introduction to this comment, it is important for the NOSB to consider the difference between materials that are necessary to the production of an organic product (such as yeast in bread and bacterial cultures in yogurt), and materials that are convenient or useful. Our 2016 survey results show that 70% of consumers do not think that non-organic ingredients should be added to organic foods if they are not deemed essential.

We do not believe an ingredient should be considered essential or necessary if its function is for consumer convenience (e.g., adding carrageenan so consumers don't have to shake a beverage), recreating a certain texture in foods (e.g., adding carrageenan to recreate the "fatty mouthfeel" of cream in foods that contain no cream), as a binder (e.g., adding carrageenan to bind deli meats such as turkey), or for any use other than those necessary to the production of an organic product, such as with the bread and yogurt examples referenced above. We do not believe there is currently any organic product on the market which could not be made without the use of carrageenan. For example, a manufacturer may claim that carrageenan is essential for its whipping cream even as a quick scan of whipping cream products in stores shows plenty of products without it.

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[7] Bhattarachyya, S., O'Sullivan, I et al. (2012) Exposure to the common food additive carrageenan leads to glucose intolerance, insulin resistance and inhibition of insulin signalling in HepG2 cells and C57BL/6J mice. *Diabetologia* 55(1): 194-203.

Bhattacharyya, S., Feferman, L. et al. (2015) Exposure to Common Food Additive Carrageenan Alone Leads to Fasting Hyperglycemia and in Combination with High Fat Diet Exacerbates Glucose Intolerance and Hyperlipidemia without Effect on Weight. *Journal of Diabetes Research*. http://dx.doi.org/10.1155/2015/513429

[8] http://www.diabetes.org/in-my-community/local-offices/chicago-illinois/research.html and https://clinicaltrials.gov/ct2/show/NCT02629705

Given consumer demand for organic foods without potentially harmful ingredients, many companies have responded by eliminating carrageenan from their product formulations. These actions reinforce that carrageenan is not essential to organic handling.

Responding to specific questions and comments by the Handling Subcommittee:

"1. After the last review in 2012 we know some companies pledged to remove carrageenan from their products. Has this been successful and what alternatives have been used? Are there any products for which it has not been successful, and why?"

This question aims to find out whether carrageenan is essential. When the NOSB reviews company responses to this question, we urge you to consider an ingredient to be essential only when a product cannot be made without it. For example, a company may claim that carrageenan is essential in heavy cream, yet plenty of heavy cream on the market – both organic and conventional – does not contain it. An ingredient is not essential merely on the basis of it being useful for marketing or consumer convenience.

"2. Are there any stakeholders who rely on this material? If so for what uses and why have alternatives not been successful?"

This seems to be a repeat of question 1. See answer above.

Stakeholders also rely on carrageenan being absent from organic foods. Many consumers who are aware of the potential for negative health impacts from consuming carrageenan look for foods without it. Organic foods should provide that assurance, without consumers having to check the ingredients list to make sure the organic foods they buy are free from carrageenan. One of OFPA's purposes is to ensure consumers that organically produced products meet a consistent standard. Organic foods should be consistently free from any non-organic food additive that raises potentially serious health concerns.

"3. Is "sensitivity" to a food ingredient enough of a reason to prohibit a substance in organic products if it is clearly listed on a food label?"

In the body of the text: "It does come down to a core question of philosophy about the organic regulations: if humans have varying degrees of sensitivity to carrageenan in the diet, is that enough reason to prohibit it?"

"Humans are also sensitive to gluten, dairy, legumes, and many other foods; is that reason enough to keep them out?"

Referring to the potential health effects of carrageenan as a "sensitivity" issue is a mischaracterization of the scientific findings regarding the potential human health effects of carrageenan. While it indeed seems to be the case that, anecdotally, many individuals have found relief from conditions such as irritable bowel syndrome and certain gastrointestinal diseases after eliminating carrageenan from their diet, the removal of carrageenan from the National List should be based on the scientific studies pointing to inflammation, ulcerative colitis-like disease, intestinal lesions and ulcerations in some animals as well as the animals studies that have shown carrageenan may act as a promoter of colon tumors. The studies on diabetes that have been published recently and the ongoing research on this topic should also be considered.

To answer the Handling Subcommittee's embedded question: no, gluten, dairy and legumes should not be prohibited from organic foods because some individuals are sensitive. Gluten, dairy and legumes are not non-organic food additives that can be placed on the National List; carrageenan is an additive that is otherwise prohibited in organic foods. The NOSB should evaluate carrageenan to the OFPA criteria to determine if it meets the criteria to be listed as an allowed material for the next five years. Foods that contain gluten or fall in the category of dairy or legumes do not undergo evaluation to OFPA criteria because they are actual foods that can be produced organically.

Summary

We strongly urge the NOSB to remove carrageenan from the National List. Research points to serious potential health effects: laboratory research has shown ulcerative colitis-like disease and intestinal lesions and ulcerations in some animals, studies in animals have shown carrageenan may act as a promoter of colon tumors, and studies with human cells point to carrageenan's role in inflammation. Carrageenan is not an essential material, as any product containing carrageenan can be made without it.

Sunset Review: Beta-Carotene Extract

Beta carotene extract is used as a color additive and fails to meet the essentiality criterion. We urge the NOSB to remove it from the National List.

Coloring is not an essential processing step for making organic foods, and it is therefore questionable whether any non-organic food ingredient whose primary or only function is to color foods should be deemed "essential." The sunset review of 17 colors in Fall 2015 revealed that certified organic colors, derived from organic crops, are now widely available to handlers. So for the food manufacturers that wish to color their foods, it appears organic options are available.

The NOSB also should send a clear message to handlers and food coloring manufacturers that organic colors should be used. Removing non-organic colors from the National List sends a message of support for the development of organic sources of color for organic foods.

We urge the NOSB to remove beta-carotene extract as a color additive from the National List.

Proposal: Oat Beta Glucan

We oppose listing oat beta glucan because it fails the OFPA criteria of essentiality and compatibility with organic handling.

According to our 2016 survey, 70% of consumers think the USDA should not permit the use of non-organic ingredients that are not deemed essential. Oat beta glucan appears to be added to foods to increase fiber content which is not an essential or necessary processing step to create organic foods. Even if increasing fiber content were considered essential in processing organic foods, there are plenty of organic sources of fiber available. We agree with the Handling Subcommittee that oat beta glucan should not be added to the National List because it fails the essentiality criterion.

We also believe that oat beta glucan fails the "compatibility and consistency" criterion. Made from non-organic oats, it may be produced in ways that are incompatible with organic farming practices, including possible field and storage applications of pesticides and fumigants that would not be permitted in organics. The use of non-organic oats as an additive in organic processed foods, when whole organic oats are so readily available, would create inconsistency in the organic label and organic standard.

We urge the NOSB to reject the petition to add oat beta glucan to the National List.

Proposal: Sodium dodecylbenzene sulfonate (SDBS)

SDBS is petitioned as an active ingredient in an antimicrobial formulation for use in treating fruits and vegetables in the premises of organic food retail establishments. It is petitioned as a processing aid, not an ingredient. We noted, however, that there is no Technical Report (TR) available for this material. For any material petitioned to be added to the National List, and especially for an antimicrobial material like SDBS, the NOSB should not vote to list it on the National List without a TR.

Proposal: Ancillary Substances

The NOSB should review all ingredients that end up in organic foods to OFPA criteria. This includes ingredients of ingredients, also referred to as "ancillary substances." As we have noted repeatedly in past comments, we believe that OFPA does not distinguish between "ingredients" and "ingredients of ingredients," "other ingredients" or "ancillary substances" in organic foods. According to OFPA, any non-organic ingredient not appearing on the National List shall not be added to organic products during processing or any post harvest handling, and this includes ingredients of formulated, multi-ingredient materials appearing on the National List.

Our surveys consistently show that consumers expect organic foods to be free from artificial ingredients. Our most recent survey on this issue found that 91% of consumers think artificial materials or chemicals should not be used during processing of organic foods, and 89% of consumers think that the organic label on packaged and processed foods should mean no artificial ingredients or colors were used.

OFPA also specifies that the National List "shall contain an itemization, by specific use or application, of each synthetic substance permitted" (Sec. 2118 [7 U.S.C. 6517]). This would allow the NOSB to restrict the approval of certain materials to use as a component of a specific ingredient. For example, a particular preservative or carrier could be approved only for use in microorganisms, pectin and/or yeast.

The Handling Subcommittee, with its current proposal, is pursuing a different approach to dealing with ancillary substances in the formulated multi-ingredient products that are on the National List. Attention to this issue has led to improvements, including improved transparency and a closer look at ancillary substances during the petitioning and sunset review process. We appreciate the subcommittee's proposal that ancillaries on IARC or NTP lists should not be allowed. This would prohibit formaldehyde and BHA. However, the NOSB and NOP can and should do more to ensure that all ingredients in organic foods have undergone NOSB review to OFPA criteria.

We do not support the current proposal by the Handling Subcommittee, which is not consistent with the requirements in OFPA and could lead to approval of unreviewed ancillary substances, including materials that would not meet OFPA criteria for use in organic foods. Specifically, the Handling Subcommittee proposes: "The vote to approve a new substance will be considered to also approve the ancillaries that are associated with that substance unless the NOSB specifically states that one is not approved." This could lead to the use of ancillary substances that have not been reviewed.

We also disagree with the proposal that "Any ancillary substances that the NOSB wishes to prohibit (that are not already on the IARC and NTP lists) will have to come before the board in a

separate proposal that can be voted on at the same meeting or a subsequent meeting of the board." We do not believe that the manufacturers can be counted on to bring forward information about ancillary substances if the result might be that they are reviewed and prohibited. We recommend striking this part of the proposal.

Moving forward, we believe it is crucial to perform a thorough market survey to obtain a comprehensive and complete list of ancillary substances used. The current approach, of relying on manufacturers to disclose their ancillary substances, is not working. We then urge the NOSB to review these materials to OFPA criteria to determine whether they are not harmful to human health and the environment, essential, and compatible with organic handling. Only a review by NOSB can answer these crucial questions.

Discussion Document: Nutrient Vitamins and Minerals

We appreciate the Handling Subcommittee's continued work to fix the inappropriate listing and annotation for "nutrient vitamins and minerals" on the National List, and its careful consideration of different options. We hope that this issue will be resolved soon, and we agree with the Handling Subcommittee members who believe that the past decisions of the NOSB regarding petitioned nutrients for infant formula need to be acted upon by the NOP as soon as possible.

As we noted in our Fall 2015 comment: "Only synthetic and non-organic nutrient additives that are required by FDA to be added to a specific food should be considered necessary in the production of an organic version of that food."

We also continue to believe that individual nutrient additives that are necessary to the production of organic foods should be individually petitioned, reviewed, and listed only when all OFPA criteria, including essentiality, are met.

The proposal that comes closest to meeting OFPA criteria is Option #1, but it is very complicated, and we see two problems with it. First, it cross-links to FDA regulations, which is problematic because it cedes authority over this listing in the National List to another agency. Second, it continues to list a broad category ("vitamins and minerals") rather than individual materials. We believe the intent of the National List is to list individual materials, not categories.

We believe that the best solution would be a listing for "as vitamins and minerals:" in both 7 C.F.R. § 205.605(a) and (b) with the specific vitamins and minerals that have been reviewed listed underneath, similar to how section 205.601 is organized. This will ensure NOSB review to OFPA criteria of every material.

As we have noted in past comments, many synthetic and non-organic nutrients already appear individually on the National List, and only a handful that would be considered essential would need to be petitioned and reviewed.

Comments on Option #1

As we understand Option #1, it suggests three different listings for vitamins and minerals: two for synthetic vitamins and minerals and one for nonsynthetic vitamins and minerals. The result of the annotations would be that synthetic vitamins and minerals would be allowed in food only when required by law or to meet an FDA standard of identity in which they are incorporated. Vitamins and minerals could still be added to other products but those would be labeled as "made with organic ingredients" and not "organic." This includes infant formula, which would be labeled "made with organic ingredients." Vitamins that are not synthetic would be placed on section 205.605(a) and those that are identified as essential in 21 C.F.R. § 101.9 for food and 21 C.F.R. § 107.100 and 107.10 for infant formula would be allowed in foods labeled "organic."

Although it comes closest to meeting OFPA requirements, we do not support Option #1 for several reasons.

We do not think referencing FDA regulations is the best approach, since it gives authority to another agency whose standards and criteria differ from those in OFPA. We think referencing FDA regulations is appropriate only when a certain product could not be sold as organic without meeting certain FDA regulations, as is the case with infant formula. The FDA has stated in Guidance for Industry in November 2015 that it does not require any vitamin or mineral to be added to foods, other than infant formula.[9]

We do not agree that "the public's concern is primarily with synthetic vitamins and minerals" and that the standards for non-synthetic vitamins and minerals should be different. All are non-organic materials that need to be reviewed to OFPA criteria. Our survey results show that 70% of consumers think that non-organic ingredients should be allowed in organic foods only when they are deemed to be essential. We specifically asked consumers about "non-organic ingredients" rather than "artificial" or "synthetic" ingredients.

Consumer Reports proposal for "vitamins and minerals"

Only vitamins and minerals that are required to be added to the food by law or to meet an FDA standard of identity can be deemed essential to creating an organic version of the food.

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http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm470756.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

Many vitamins and minerals already appear on the National List. These include:

205.605(a) non-synthetics allowed

Vitamins and minerals:

Calcium carbonate	*(Calcium)*
Calcium chloride	*(Calcium and Chloride)*
Calcium sulfate - mined	*(Calcium)*
Magnesium sulfate	*(Magnesium)*
Potassium chloride	*(Potassium and Chloride)*
Potassium iodide	*(Potassium and Iodine)*

205.605(b) synthetics allowed

Vitamins and minerals:

Acids (citric)	*(Vitamin C)*
Ascorbic acid	*(Vitamin C)*
Calcium citrate	*(Calcium)*
Calcium hydroxide	*(Calcium)*

Calcium phosphates (monobasic, dibasic, and tribasic)
(Calcium and Phosphorus)

Ferrous sulfate - for iron enrichment or fortification of foods when required by regulation or recommended (independent organization)
(Iron)

Magnesium carbonate - for use only in agricultural products labeled "made with organic (specified ingredients or food groups(s))," prohibited in agricultural products labeled "organic"
(Magnesium)

Magnesium chloride - derived from sea water
(Magnesium and Chloride)

Magnesium stearate - for use only in agricultural products labeled "made with organic (specified ingredients or food groups(s))," prohibited in agricultural products labeled "organic"
(Magnesium)

Tocopherols - derived from vegetable oil when rosemary extracts are not a suitable alternative
(Vitamin E)

The following vitamins and minerals would be candidates for petition and NOSB review:

Vitamin A
Vitamin D

Vitamin B2 / Riboflavin
Vitamin B12

Infant formula

For infant formula, we support the proposal in Option #1, Proposed Annotation #2 and #3 with one modification. We believe it is appropriate to reference FDA regulations for infant formula, since the nutrients specified in 21 C.F.R. § 107.100 are required. However, we believe that referencing 21 C.F.R. § 107.100 alone is sufficient, and that referencing both 21 C.F.R. § 107.100 and 21 C.F.R. § 107.10 may lead to a repeat of the problems previously encountered when 21 C.F.R. § 104.20 was referenced. Since 21 C.F.R. § 107.100 specifies the nutrients that are required, this reference alone suffices.

Summary

We propose listing "vitamins and minerals" as a category in both 7 C.F.R. § 205.605(a) and (b) with individual vitamins and minerals listed underneath after they have undergone full review to OFPA criteria.

For infant formula, a categorical listing and reference to FDA regulations is appropriate, since FDA requires the addition of certain nutrients to infant formula. For infant formula, we support Option #1 with one modification: referencing 21 C.F.R. § 107.100 rather than referencing both 21 C.F.R. § 107.10 and 21 C.F.R. § 107.100.

Additional comment: phosphate food additives in organics

We appreciate the Handling Subcommittee's request for a new technical review (TR) to better understand the recent scientific studies that raise concerns regarding public health impacts of phosphate food additives. Prior to the Fall 2015 meeting, we urged the NOSB to table the vote until after the TRs became available. This did not happen, as the NOSB voted on these materials and voted to relist them. We remain concerned with the phosphate food additives on the National List. When the TR is received, we urge the Handling Subcommittee to place the three materials back on the agenda to complete the proper review process.

Crops Subcommittee

Petition - Ash from manure burning

We urge the NOSB to reject the petition for an annotation change to "ash from manure burning" listing. We believe all ash from manure burning should remain prohibited in organic production. We agree with the Crops Subcommittee that "utilizing burning as a method to recycle millions of pounds of excess poultry manure inadvertently supports the business of CAFOs by creating an organic industry demand for ash" and that the annotation change fails to meet OFPA criteria.

Discussion Document - EPA List 4 Annotation Change

Prohibition of NPEs in Inerts - Annotation Change

We support the Crops Subcommittee's proposal to remove nonylphenol ethoxylates (NPEs) from use in organic agriculture, and urge the NOSB to recommend an end to their use.

Memorandum of Understanding between NOP and EPA

We support the involvement of the Environmental Protection Agency (EPA) and its Safer Choice program in reviewing inert ingredients in pesticide formulations; however, we also believe that NOSB and NOP should make the final determination regarding which "inerts" can be used in organic production, according to OFPA criteria. We urge the NOP and EPA to draft a Memorandum of Understanding (MOU) detailing the interaction between the NOP and EPA in the review of inerts, and detailing how the NOSB and NOP will determine which inerts on the Safer Choice list meet OFPA criteria and will be allowed in organic production.

Consumer Reports would again like to thank the NOSB for its continuing dedication to its mission and for its efforts to maintain the integrity of the organic label.

Thank you for considering our comments.

Respectfully submitted,

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