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National Organic Standards Board
USDA-AMS-NOP
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1400 Independence Ave., S.W.
Washington, DC 20250

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Comments of Consumers Union to the National Organic Standards Board on the Spring 2017 Meeting
Docket No. AMS-NOP-16-0100

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Consumers Union, the policy and mobilization arm of Consumer Reports, welcomes the opportunity to submit written comments on the proposals and discussion documents for the spring 2017 meeting of the National Organic Standards Board (NOSB) in Denver, Colorado.

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 and sustainable food system.

Our vision is for consumers to have access to a safe, transparent, and sustainable food system that robustly supports human and environmental health.

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 label, to empower consumers with knowledge to make better and more informed decisions when shopping for food. This information is available to consumers online at www.greenerchoices.org.

We rate the USDA organic label as "meaningful" on processed foods and foods derived from animals and "highly meaningful" on produce and minimally processed foods. The government regulations and the National Organic Program

at the USDA have fostered the growth of an alternative food production system backed by regulations that protect human health and the environment.

In the federal organic regulations and in USDA educational materials, organic production is defined as a system that integrates "cultural, biological, and mechanical practices that foster cycling of resources, promote ecological balance, and conserve biodiversity."[1] The standards should assure consumers that organic farms adopt these practices and achieve these goals.

In our publications, both print and online, we point out to consumers the value of the USDA Organic label when shopping for food. When this organic label falls short, we advocate for the USDA and the NOSB to strengthen the standards.

In many ways, our vision for a safer and more sustainable food system aligns with the organic system. The USDA Organic label communicates to consumers that the food was produced on a farm that adheres to a comprehensive set of government standards designed to support a system of sustainable agriculture. The integrity of the organic label is worth protecting and, where warranted, its standards should be improved. This is why the work of the National Organic Standards Board is so important, and why we appreciate your work and dedication to the organic label.

[1] §205.2 and USDA fact sheet: Agricultural Marketing Service's National Organic Program. Available online: www.ams.usda.gov/sites/default/files/media/About%20the%20National%20Organic%20Program.pdf.

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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 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, which we submit to 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.

Our surveys show that 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 percent of consumers. An overwhelming majority (86 percent) of consumers expect organic foods to be free from artificial ingredients and colors.

Material Review - The Importance of OFPA Criteria

An overwhelming majority of consumers expect organic foods to be free from synthetic ingredients, 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, both those that are petitioned and those that are up for sunset review, 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.

Essentiality

One criterion in OFPA for materials review is essentiality, or necessity. 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 but not necessary, such as sodium phosphate.

Too often, the use of a particular material by at least one food handler is considered to satisfy the criterion of essentiality or necessity. We disagree. A material should only meet the criterion if it is actually essential or necessary to the production of an organic version of a certain product.

In our 2016 consumer survey, we specifically asked consumers about essentiality, and 70 percent responded that the USDA should not permit the use of non-organic ingredients in organic food production if the ingredient is not deemed essential.

For the spring 2017 meeting, we urge the board to consider this when evaluating the petition for short DNA tracers and the sunset review of sodium phosphate. Neither of these substances is necessary for the production of organic foods.

Handling Subcommittee

Sunset Review: Sodium Phosphate

We do not support the relisting of sodium phosphate, due to human health concerns and a lack of essentiality. We previously expressed our concern with the human health impacts of phosphate food additives in our fall 2015 and spring 2016 comments.

We noted in those comments the recent findings that a high intake of phosphorus is associated with negative impacts on bone health, kidney health, and heart health.[2] Research also shows that phosphate food additives are more readily absorbed during digestion and lead to a higher phosphorus load, compared with phosphorus found naturally as a component of foods.[3]

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[2] Guiterrez, O.M. (2013) The connection between dietary phosphorus, cardiovascular disease and mortality: where we stand and what we need to know. Adv. Nutr. 4: 723-729. doi:10.3945/an.113.004812.

[3] Ritz, E., Hahn, K. et al (2012) Phosphate additives in food—a health risk. Dtsch Arztebl Int 109(4):49–55. doi:"10.3238/arztebl.2012.0049.

No single, isolated phosphate food additive, including sodium phosphate, can be implicated as an isolated risk factor; rather, it is the widespread use of phosphate food additives that gives rise to human health concerns.

Phosphate food additives, as a category, fail to meet the human health criterion in OFPA. Each individual phosphate food additive, therefore, should be reviewed on the basis of essentiality in organic food production.

If a product can be made without a phosphate food additive, it is not essential. The prohibitions on sodium phosphate in European, Japanese, Codex, and IFOAM standards strongly suggest that sodium phosphate is not essential in the production of organic foods.

We urge the NOSB to remove sodium phosphate from the National List.

Petition: L-methionine

We are not opposed to adding L-methionine to the National List with the annotation, “For use in nutritionally complete pediatric enteral formulas based on soy protein.” L-methionine is an essential amino acid, and pediatric soy-based enteral formulas would be nutritionally deficient without it.

L-methionine already is used in products labeled organic. It is not appropriate to consider L-methionine as an allowed synthetic under the “nutrient vitamins and minerals” listing, because L-methionine is an amino acid, not a vitamin or mineral. We have long argued that the “nutrient vitamins and minerals” listing has been inappropriately interpreted by the National Organic Program (NOP) in the past and has led to the use of synthetic nutrients that should be individually reviewed by the NOSB and approved by the NOP before use in organic foods. The petition for L-methionine, with a narrow annotation to restrict its use to products in which it is essential for nutritional reasons, is appropriate.

The NOSB should encourage other manufacturers who wish to use synthetic or non-organic nutrients in organic foods to petition for the inclusion of those that are not already individually listed on the National List.

Furthermore, we urge the NOSB to continue working toward a resolution of the “nutrient vitamins and minerals” listing. The Handling Subcommittee shared a discussion document for public review prior to the spring 2016 meeting and gathered public comment on the best option for an annotation change. This issue was not on the agenda for the fall 2016 meeting and is again not on the agenda for the spring 2017 meeting. We hope that the new board members will become familiar with this topic and its history and work toward a solution.

The current “nutrient vitamins and minerals” listing has been used to add substances not on the National List to organic foods, including organic infant formula and baby foods. Handlers adding these non-approved materials have argued that they should be considered nutrients. Handlers adding these non-approved materials have argued that they should be considered "nutrients" and therefore can be added to organic foods without first going through the petition and review process for synthetic materials.

We are not alone in pointing out that the interpretation of the “nutrient vitamins and minerals” listing is not appropriate. The NOP acknowledged in a public memo in 2010 that its interpretation of the current listing for “nutrient vitamins and minerals” and its annotation referencing FDA regulations is inappropriate.[4]

The best approach would be for the group listing for “nutrient vitamins and minerals” and its annotation referencing FDA regulations to be removed from the National List. Instead, individual nutrient additives that are necessary to the production of organic foods should be individually petitioned, reviewed, and listed only when all OFPA criteria are met.

Nature’s One’s petition for L-methionine, with its proposed annotation, is a good example of how individual nutrients could be petitioned to be added individually to the National List when they are deemed essential.

Many vitamins and minerals already appear individually on the National List. We urge the Handling Subcommittee to continue its work on this important issue. Vitamin A, D, B2, and B12 would need to be petitioned. Once that is done, the “nutrient vitamins and minerals” listing could be removed during the next sunset review.

Petition: Short DNA Tracers

We urge the board to reject the petition to add short DNA tracers to the National List because they were created using excluded methods. Short DNA tracers also do not meet OFPA criteria because they are not essential and, potentially, for raising environmental and human health concerns. We agree with the Handling Subcommittee that the petition should not be approved.

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[4] National Organic Program. April 26, 2010. Action Memorandum for the Chairman of the National Organic Standards Board. Available at: www.ams.usda.gov/sites/default/files/media/NOSB%20Memo%20Scope%20of%20Nutrient%20Vitamins%20and%20Minerals.pdf.

The production of the short DNA sequences involves use of an excluded method. Under the changes to the excluded method terminology that were recently recommended by the board, the term "modern biotechnology" is defined, in part, as "the application of *in vitro* nucleic acid technologies." The use of polymerase chain reaction (PCR) technology to create large numbers of copies of a specific short DNA sequence clearly falls under this definition. The short DNA sequences, which consist of double-stranded DNA some 50 to 150 nucleotide base pairs in length, are clearly nucleic acids. If the double-stranded DNA was thousands of base pairs in length, it could constitute a full gene; the short DNA tracers are just much shorter sequences of double-stranded DNA, and the same methodologies are used to create both. The process of synthesizing huge numbers of these short double-stranded DNA sequences thus entails the use of an *in vitro* nucleic acid technique and should be considered an excluded method.

Short DNA tracers also fail the essentiality criterion since they are not necessary to the production or handling of the agricultural product. While short DNA tracers may facilitate traceability of organic products, they clearly are not necessary for their production, since organic products are presently being produced without use of the short DNA tracers. In addition, there are other forms of traceability that would not involve changes to the food itself.

In terms of environmental impacts and human safety, rather than present studies that demonstrate evidence of a lack of potential environmental or human health harms, SafeTraces simply quotes others that presume short DNA sequences are safe.

SafeTraces received a No Questions Letter from the FDA in August 2014 in response to its submitted GRAS (Generally Recognized as Safe) Notification letter. FDA's main rationale for not questioning the safety of the short DNA sequences appears not to have been based on scientific studies but, rather, "based on its ubiquity in food, FDA concluded that *nucleic acids themselves do not raise safety concerns*. … Moreover, the small size of the *nucleic acids involved would not ordinarily be expected to remain after digestion or be biologically active.*" (Italics added.)

However, recent studies have shown that very short pieces of RNA (a nucleic acid), known as micro-RNA (miRNA) or silent interfering RNA (siRNA), can not only survive digestion, but can also survive biological effects.[5] One feeding study found that specific plant miRNA survived digestion and had an

[5] Kukasik A and P Zielenkiewicz. 2017. Plant MicroRNAs—Novel Players in Natural Medicine? *International Journal of Molecular Sciences*. At: www.mdpi.com/1422-0067/18/1/9

effect on gene expression in animals.[6] Another study summarized more recent work and called for specific risk assessments for genetically engineered plants or products containing small double-stranded RNAs.[7]

Indeed, the Environmental Protection Agency's (EPA) Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP) investigated miRNAs in 2014 and concluded that they represent an issue that deserves further scrutiny as to the potential environmental and human health impacts.[8] Thus, the FDA's letter to SafeTraces should not necessarily be interpreted to be a sufficiently-researched, informed conclusion of safety. Similar studies have not been done with short sequences of DNA, so we do not know whether they can have similar impacts. Until such safety studies are done with short DNA sequences, it should not be assumed that they have no safety or environmental impacts.

Proposal: Marine Algae Listings

We support the effort to clarify and annotate the marine algae listings through use of Latin binomials. However, we do not support the first proposal, which only uses class names, and would therefore use identical annotations for agar-agar and carrageenan, which belong to the same class.

Since the board voted to remove carrageenan from the National List, we are concerned that this proposal may lead to the continued use of carrageenan under a different name.

Specifically, we urge the board to clarify that the annotations should specify the genus and species, where appropriate. For agar-agar, the annotation should specify "from genus Gelidium, Gracilaria, Pterocladia, or Gelidiella."

Proposal: Ancillary Substances in Cellulose

We appreciate the Handling Subcommittee bringing forward additional ancillary substances that were identified after the sunset review of cellulose at

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[6] Zhang L, Hou d, Chen X, Li D, Zhu L, Zhang Y, Li J, et al. 2012. Exogenous plant MIR168a specifically targets mammalian LDLRAP1: evidence of cross-kingdom regulation by microRNA. *Cell Research* 22 (1): 107-26. At: www.ncbi.nlm.nih.gov/pmc/articles/PMC3351925/

[7] Heinemann JA, Agapito-Tenfen SZ and JA Carman. 2013. A comparative evaluation of the regulation of GM crops or products containing dsRNA and suggested improvements to risk assessments. *Environment International* 55: 43-55. At: www.sciencedirect.com/science/article/pii/S0160412013000494

[8] EPA. 2014. RNAi Technology: Program Formulation for Human Health and Ecological Risk Assessment. SAP Minutes Number 2014-02. At: www.epa.gov/sites/production/files/2015-06/documents/012814minutes.pdf.

the fall 2016 meeting in St. Louis. The transparency that comes with a review of ancillary substances during sunset review is valuable.

Some of the materials identified as ancillary substances in cellulose raise concerns, such as kymene and vinyl chloride. If these materials are indeed used as ingredients in cellulose, it means that vinyl chloride and kymene could appear as unlisted ingredients in organic foods containing cellulose.

According to the MSDS for kymene, it is a hazardous substance that may cause cancer. Vinyl chloride is a classified as Group 1 (carcinogenic to humans) by the International Agency for Research on Cancer. These materials may pose danger to humans, and their use in the production of organic foods should be reviewed.

This is why we continue to argue that OFPA requires that *all* ingredients in certified organic foods must either be produced in accordance with the federal organic standards or must appear on the National List of Approved and Prohibited Substances.

If the NOSB chooses not to take this approach, it should, at the very least, specify that kymene and vinyl chloride are not allowed as ancillary substances for cellulose in organic foods.

For the benefit of new NOSB members, our position on ancillary substances, as outlined in our spring 2014 written comment, is repeated below.

According to the Organic Foods Production Act (OFPA) of 1990:

> ***SEC. 2111. [7 U.S.C. 6510] HANDLING.***
> *(a) IN GENERAL.—For a handling operation to be certified under this title, each person on such handling operation shall not, with respect to any agricultural product covered by this title—*
> *(1) add any synthetic ingredient not appearing on the National List during the processing or any postharvest handling.*
>
> OFPA does not distinguish between “ingredients” and “other ingredients” or “ancillary ingredients.” Quite simply, any synthetic ingredient not appearing on the National List shall not be added to organic products during processing or any post-harvest handling.
>
> OFPA also specifies that the National List “shall contain an itemization, by specific use or application, of each synthetic substance permitted” (Sec. 2118 [7 USC 6517]).

The National List is for single substances, not formulated multi-ingredient products. All non-organic ingredients and substances used in organic production must be on the National List.

Discussion Document: BPA in Packaging

The Handling Subcommittee writes, "organic food should be produced in a way that minimizes exposure to toxic materials in any form." We agree, and we appreciate the subcommittee's work to develop a discussion document on the topic of bisphenol A (BPA) in packaging materials.

We will not be submitting comments on this topic prior to the March 30 deadline, because we need more time to review the discussion document and develop our comments.

Livestock Subcommittee

Antibiotic Use in Organic Hatcheries

Eliminating the routine use of antibiotics in healthy food animals is a top priority for Consumer Reports. While the organic standards prohibit the routine use of antibiotics, there is an exception: The Organic Foods Production Act of 1990 allows for the use of antibiotics in chicks prior to day two of life because it exempts day-old chicks from organic management.[9]

We wrote to Secretary Vilsack in January 2014 and June 2015, requesting a clear prohibition on antibiotics at all stages of life for all farm animals used in organic food production. Vilsack responded in August 2015, writing that the USDA will be requesting that NOSB give a recommendation for antibiotic use in day-old chicks.

We continue to urge the Livestock Subcommittee to take action on this issue. From last year's Livestock Subcommittee meeting notes, it appears that the subcommittee is waiting for additional input from the NOP before starting to address this issue.

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

[9] 7 U.S.C. § 6509(e)(1).

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.

We strongly urge the NOSB's Livestock Subcommittee to begin work developing a recommendation prohibiting all antibiotic use in organic poultry production.

Certification, Accreditation, and Compliance Subcommittee

Discussion Document: Converting Native Ecosystems

We appreciate the CACS's work on the discussion document on this topic. We agree that the conversion of native ecosystems to farmland can have negative impacts on biodiversity and the environment. There is an incentive to convert previously unproductive land, which has not been farmed and, therefore, has not been treated with prohibited chemicals, to organic farmland because it eliminates the three-year conversion period.

We support the effort of the NOSB to address this important issue. However, we will not be submitting comments on this topic prior to the March 30 deadline, because we need more time to review the discussion document and develop our comments.

Materials/GMO Subcommittee

Excluded Methods Terminology

The topic of excluded methods terminology is not on the agenda for this meeting; nevertheless, we urge the board to continue the important work of updating the terminology for excluded methods.

At the fall 2016 meeting, we commented on a discussion document regarding the use of four terms in the Terminology Chart—transposon, cisgenesis, intragenesis, and agro-infiltration—that should be considered

excluded methods. We urge the Materials/GMO Subcommittee to bring a proposal to the board to ensure that these terms are also included in the terminology for excluded methods.

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." Thus, agro-infiltration is clearly an in vitro nucleic acid technique and clearly falls under the definition of "modern biotechnology." Therefore, agro-infiltration should be an excluded technique since modern biotechnology is an excluded method.

Cisgenesis and intragenesis are also forms of genetic engineering and clearly should be listed as excluded methods, as well. 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."[10] 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.[11] Both cisgenesis and intragenesis are clearly subsets of genetic engineering and clearly constitute an excluded method.

Transposons are mobile genetic elements that have been used to genetically engineer plants and animals.[12] These uses clearly constitute an excluded method since they are used in genetic engineering. Transposons can also be used to create animal vaccines. While GE vaccines are not prohibited in the organic program, due to the exemption of vaccines from the excluded methods terminology, GE vaccines should not be allowed in organic production. However, even if they are to be permitted, transposon use for creating GE plants and GE animals clearly falls under the excluded methods. At the least, transposons should be in the Terminology Chart in the Guidance on Excluded Methods with a note saying that use in vaccines for animals may be allowed.

In summary, we urge the subcommittee to bring forth a proposal to include the terms transposons, cisgenesis, intragenesis, and agro-infiltration as excluded methods.

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[10] 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

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

[12] Ivics Z and Z Izsvák. 2010. The expanding universe of transposon technologies for gene and cell engineering. *Mobile DNA*. At: mobilednajournal.biomedcentral.com/articles/10.1186/1759-8753-1-25

Conclusion

We appreciate the work of the NOSB and urge the board to:

- Remove sodium phosphate from the National List, due to lack of essentiality and human health concerns;
- Follow up on the previous work of the board on “nutrient vitamins and minerals” and prepare for removing this inappropriately interpreted listing from the National List;
- Reject the petition to add short DNA tracers to the National List because they are produced using excluded methods and are not essential;
- Clarify the proposal for marine algae listings to ensure the annotations specify the genus, especially for agar-agar;
- Carefully review the inclusion of kymene and vinyl chloride in the list of ancillary substances for cellulose and prohibit their use.

We urge the Livestock Subcommittee to start working on a proposal to prohibit the use of all antibiotics at all stages of life for poultry, to ensure that the routine of use of antibiotics is consistently prohibited in organic production.

We also hope that the GMO/Materials Subcommittee will finish its work on updating excluded methods terminology, specifically to include the terms transposons, cisgenesis, intragenesis, and agro-infiltration as excluded methods.

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.

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