



POLICY & ACTION FROM CONSUMER REPORTS

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National Organic Standards Board
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**Comments of Consumers Union to the National Organic Standards Board
on the Fall 2016 Meeting
Docket No. AMS-NOP-16-0049**

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Summary

Consumers Union, the policy and mobilization arm of Consumer Reports,¹ welcomes the opportunity to comment on proposals and discussion documents posted for the Fall 2016 meeting of the National Organic Standards Board (NOSB) in St. Louis.

We urge the NOSB to consider *all* criteria, as specified in the Organic Foods Production Act of 1990 (OFPA), during material reviews (new petitions and sunset reviews). Materials that fail to meet every criterion should not be allowed in organic production. Proper review of materials is critical to preserving the integrity of the organic label and ensuring it meets consumer expectations.

¹ Consumers Union is the policy and mobilization arm of Consumer Reports. Consumers Union is an expert, independent, nonprofit organization whose mission is to work for a fair, just, and safe marketplace for all consumers and to empower consumers to protect themselves. It conducts this work in the areas of food and product safety, telecommunications reform, health reform, financial reform, and other areas. Consumer Reports is the world's largest independent product-testing organization. Using more than 50 labs, auto test center, and survey research center, the nonprofit organization rates thousands of products and services annually. Founded in 1936, Consumer Reports has over 7 million subscribers to its magazine, website, and other publications.

For the Handling Subcommittee agenda items, we urge the NOSB to:

- Remove carrageenan from the National List, because scientific studies point to negative health impacts
- Remove all phosphate food additives from the National List, with the possible exception of monocalcium phosphate as a leavening agent
- Address the "nutrient vitamins and minerals" listing, and put this issue back on the agenda
- Reject the petition to add oat protein concentrate to the National List
- Remove the color additive beta carotene from the National List

We urge the Livestock Subcommittee to address the issues of antibiotic use in hatcheries and day-old chicks, and to begin work on a recommendation for poultry genetics.

We are submitting the full reports for four of our surveys (March 2014, June 2014, 2015 and 2016) in response to the Materials Subcommittee's request for research on consumer demand. We support the Materials/GMO Subcommittee's proposal on Excluded Methods Terminology and offer comments on the third discussion document, specifically that four of the terms in the Terminology Chart—transposon, cisgenesis, intragenesis and agro-infiltration—should be considered excluded methods.

We urge the NOSB to vote on the question of whether to allow products of hydroponic operations to be labeled as “organic,” and to reject this proposal. We are not opposed to hydroponic food production, but we do not believe it should be labeled "organic."

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NOSB's role in preserving 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. Proper material review, 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

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. An overwhelming majority (86%) of consumers expect organic foods to be free from artificial ingredients and colors.

When we asked consumers about essentiality, 70% responded that the USDA should not permit the use of non-organic ingredients in organic food production if the ingredient is not deemed essential.²

² Consumer Reports National Research Center, *Natural Food Labels Survey: 2015 Nationally-Representative Phone Survey*, Survey Research Report (Jan. 29, 2016) (online at www.consumerreports.org/content/dam/cro/magazine-articles/2016/March/Consumer_Reports_Natural_Food_Labels_Survey_2015.pdf).

Material review - the importance of OFPA criteria

Given that an overwhelming majority of consumers expect organic foods to be free from synthetic ingredients, and that this expectation is rooted in the organic law and regulations, consumers 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 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 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.

We include our full discussion of the importance of meeting all OFPA criteria in Appendix A of this comment.

Essentiality

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.

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 of essentiality or necessity 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% responded that the USDA should not permit the use of non-organic ingredients in organic food production if the ingredient is not deemed essential.

Sunset review

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 has reduced 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.

Handling Subcommittee

Sunset Review: Carrageenan

We strongly urge the NOSB to remove carrageenan from the National List. Foods should contain only ingredients that are safe for human health. Consumers especially expect this from foods labeled "organic"; this expectation is rooted in OFPA, which requires that prohibited materials may not be added to the National List for a five-year period unless it is demonstrated that the use of such substances would not be harmful to human health.

Scientific studies raise serious concerns with the safety of carrageenan and its impact on human health. Research shows that the type of carrageenan used in foods can cause inflammation.³ Laboratory research in animals has shown ulcerative colitis-like disease and intestinal lesions and ulcerations in some animals.⁴ Additional studies in

³ 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-cell 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.

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.

⁴ 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.

animals have shown carrageenan may act as a promoter of colon tumors.⁵ It is important to note that the studies showing that carrageenan may promote tumors used undegraded carrageenan, the type used as a food ingredient.

Moreover, research, including industry-sponsored research, shows that consuming foods with carrageenan can expose consumers to degraded carrageenan,⁶ which is classified as possibly carcinogenic to humans (group 2B) by the World Health Organization's International Agency for Research on Cancer (IARC).⁷

Recent research suggests that carrageenan may also contribute to insulin resistance and to the development of Type 2 diabetes.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

⁵ 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.

Arakawa, 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.

⁶ 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

⁷ International Agency for Research on Cancer (IARC), Agents Classified by the IARC Monographs, Volumes 1-110. <http://monographs.iarc.fr/ENG/Classification/ClassificationsGroupOrder.pdf>

⁸ Bhattacharyya, 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>

substantial body of scientific literature points to potential harm to human health. We urge the NOSB, when faced with conflicting findings, to use the Precautionary Principle – when numerous well-designed studies by non-industry funded scientists point to harmful effects, the NOSB should err on the side of caution and protect the safety and health of consumers.

Please note that we are not commenting on the potential negative environmental impacts of carrageenan production and seaweed harvesting. OFPA lays out mandatory criteria that materials on the National List must be evaluated against, and requires that all criteria be met. Carrageenan fails the human health criterion, which provides the basis for its removal from the National List.

Critique of the 2016 Limited Scope Technical Review by OMRI and evaluation of critical studies missing from the TER

We are concerned that the 2016 Limited Scope Technical Evaluation Report (TER) on carrageenan, by the Organic Materials Review Institute (OMRI), omitted important studies and study findings, which may impact the NOSB's decision-making process.

1. Difference between carrageenan and poligeenan

The Handling Subcommittee asked about the difference between carrageenan and poligeenan. It should be noted that "poligeenan" is a term officially adopted by the industry in 1988.⁹ It appears to be a term used to deflect attention from the fact that food-grade carrageenan and degraded carrageenan are not two distinct substances; referring to degraded carrageenan as poligeenan when discussing the health effects of carrageenan implies that these substances are distinct when in fact it has been shown that food-grade carrageenan can contain varying levels of degraded carrageenan. This is important, since it was degraded carrageenan, not "poligeenan," which was evaluated by IARC and classified as a possible human carcinogen.

Yet, OMRI writes in the TER that poligeenan is "a distinctly different substance from carrageenan," that it has "an average molecular weight of 10-20 kDa" and that it is "also called degraded carrageenan." This characterization is confusing. There is no common definition or agreement on the molecular weight of poligeenan. It is therefore incorrect to imply that poligeenan is both "distinctly different from carrageenan" and the same as "degraded carrageenan."

It is also not correct to imply that degraded carrageenan has a molecular weight of 10-20 kDa. OMRI writes that poligeenan is also called degraded carrageenan, and defines it as having a molecular weight of 10-20 kDa, but there is no agreement on this point.

⁹ Stanley, N. "Carrageenans." In: Food Gels. Ed. by Peter Harris. London: Elsevier Applied Science. Pg. 113.

IARC never uses the term "poligeenan," and defines "degraded carrageenan" as having a molecular weight of 20-40 kDa. The European Union did not use the term "poligeenan" in its 2003 evaluation, and defined "degraded carrageenan" as having a molecular weight of below 50 kDa. Japanese industry scientists, in an attempt to measure levels of degraded carrageenan in carrageenan ingredients, did use the term "poligeenan," but defined it as having a molecular weight of 20-30 kDa. Researchers at the Nestle Research Centre use the term poligeenan, and define it as having an average molecular weight of 10-30 kDa, but they measured levels of degraded carrageenan, defined at less than 50 kDa, to determine the feasibility of the European Commission's proposed specification.

Despite the lack of agreement on the definition of "poligeenan," OMRI uses the term "poligeenan" in the TER, even when discussing findings of degraded carrageenan with a higher molecular weight than 10-20 kDa. This only adds confusion to the discussion. For example, OMRI writes that "poligeenan ... [is classified] by the International Agency for Research on Cancer (IARC) as a possible human carcinogen."¹⁰ This statement is incorrect, as IARC did not evaluate the carcinogenicity of poligeenan (10-20 kDa); rather, IARC evaluated the carcinogenicity of degraded carrageenan, and defined it as having a molecular weight of 20-30 kDa.¹¹ In IARC's evaluation, studies with carrageenan with a molecular weight of 20-40 kDa were classified as "degraded carrageenan" and were included in the evaluation of degraded carrageenan's carcinogenicity.¹² It is critically important for the NOSB to understand that IARC did not classify poligeenan (10-20 kDa) as List 2B, since IARC did not evaluate poligeenan. Rather, IARC evaluated degraded carrageenan, with a molecular weight of up to 40 kDa, and classifies it as List 2B or possibly carcinogenic to humans. It is not correct to imply that the substance classified as possibly carcinogenic to humans is "a distinctly different substance from carrageenan." The substance classified as possibly carcinogenic to humans is degraded carrageenan, which is carrageenan with a low molecular weight.

In the same paragraph to answer the question about the difference between carrageenan and poligeenan, the TER then mentions one study to discuss the possibility that degraded carrageenan appears in carrageenan used as a food ingredient. This 2010 study by Uno, Omoto et al., of the Japanese carrageenan manufacturer San-Ei Gen, F.F.I., measured low molecular weight carrageenan in food-grade carrageenan. The authors reported in the abstract of the study the *average* molecular weight, rather than the levels of low molecular weight carrageenan.¹³ Average molecular weight measurements are not

¹⁰ Technical Evaluation Report. Compiled by OMRI for the USDA National Organic Program. February 10, 2016. lines 19-20, 27-28

¹¹ International Agency for Research on Cancer (IARC), Agents Classified by the IARC Monographs, Volumes 1-110. <http://monographs.iarc.fr/ENG/Classification/ClassificationsGroupOrder.pdf> page 81

¹² International Agency for Research on Cancer (IARC), Agents Classified by the IARC Monographs, Volumes 1-110. <http://monographs.iarc.fr/ENG/Classification/ClassificationsGroupOrder.pdf> page 85

¹³ Uno, Y., Omoto, T., et al. (2001) "Molecular weight distribution of carrageenans studied by a combined gel permeation/inductively coupled plasma (GPC/ICP) method." *Food Additives and Contaminants* 18(9): 763-772.

relevant, because the presence of a small number of large molecules (and carrageenan may have molecular weight in the millions of daltons) may obscure a significant low molecular weight fraction.¹⁴ In the body of the article, but not reported in the abstract or in the TER, the results of this study's tests show three of the 29 samples contained degraded carrageenan (defined by the authors as 20-30 kDa) around the detection limit (defined as "about 5%").¹⁵ The authors wrote: "This suggested that some food-grade refined carrageenan might contain about 5% poligeenan [degraded carrageenan]."¹⁶ Yet, despite these findings that some samples contained around 5% degraded carrageenan, this study has been used by the carrageenan industry to dispute the concerns about the presence of degraded carrageenan in food-grade carrageenan.¹⁷

The TER also briefly mentions the tests performed by Marinalg, the European trade group for carrageenan manufacturers, but does not discuss the results. In response to the 2003 decision by the European Commission's Scientific Committee on Food to limit the presence of degraded carrageenan to less than 5%, Marinalg attempted to measure the amount of carrageenan with a molecular weight of less than 50 kDa. Various laboratories and various test methods were used.¹⁸ These test results were not published in a journal, and complete results are not publicly available. The Marinalg report discusses findings of wide variability between laboratories, and the group concluded that testing is unreliable, which is mentioned in the TER. The TER does not mention that levels of low molecular weight carrageenan (less than 50 kDa) were found in at least one of the eleven carrageenan sample by all six testing laboratories. All but one laboratory found levels at or above 5% in multiple samples (the Danisco lab found degraded carrageenan in only one sample). And at least one laboratory found levels at or above 5% for 9 of the 11 samples. One laboratory measured 25% degraded carrageenan in one sample.¹⁹

Another industry-funded study pointing to the presence of degraded carrageenan in carrageenan ingredients was not included in the TER. In 2007, Spichtig and Austin of the Nestle Research Centre in Switzerland reported their testing method for measuring the low molecular weight tail of food-grade carrageenans, and their results.²⁰ They measured low molecular weight carrageenan using high performance size exclusion chromatography (HPSEC).²¹ They defined low molecular weight carrageenan as having a

¹⁴ Tobacman 2001 page 993.

¹⁵ Uno, Y., Omoto T., *et al* (2001), page 769, Table 2.

¹⁶ Uno, Y., Omoto T., *et al* (2001), page 768.

¹⁷ See, for example, Technical Evaluation Report. Compiled by OMRI for the USDA National Organic Program. February 10, 2016., page 1 of 8.

¹⁸ Marinalg working group, and see also Spichtig and Austin, page 82

¹⁹ Marinalg working group. page 4-5.

²⁰ Spichtig V and Austin S (2008) Determination of the low molecular weight fraction of food-grade carrageenans. *J Chromatogr B Analyt Technol Biomed Life Sci.* 861(1):81-7.
<http://www.ncbi.nlm.nih.gov/pubmed/18055280>

²¹ Spichtig and Austin (2008), page 82.

molecular weight of less than 50 kDa. When they tested the carrageenan ingredients (rather than a finished product containing carrageenan), they found that "in half of the cases the low molecular weight tail exceeds the 5% "if feasible" [less than 50 kDa] limit proposed by the European Scientific Committee on Food."²² They wrote: "Increasing the proposed limit to around 7 or 8% would probably allow carrageenan producers to more easily reach this target."²³ This study also measured the low molecular weight tail of carrageenan in a jelly product, reported at 5.8%. When acidic and flavoring components were added to the jelly, the low molecular weight tail increased from 5.8% to 6.4%.²⁴

These three industry-funded studies show that the question is not *whether* carrageenan ingredients contain degraded carrageenan, but rather *how much*. This is an important point, since degraded carrageenan with a molecular weight of 20-30 kDa (although some studies using carrageenan with a molecular weight of 20-40 kDa were included) has been classified as a possible human carcinogen by IARC.

2. Degradation of carrageenan in the digestive system

The TER includes several studies that point to degradation of carrageenan in the digestive system. Carrageenan hydrolyzes (breaks down to a smaller molecular weight) when treated with acid. The fluids in the human stomach are acidic, with a normal pH range between 1.5 and 3.5.²⁵

Another study worth noting, which was not included in the TER, is the 2007 study by Spichtig and Austin of the Nestle Research Centre in Switzerland. They write: "it appears that pH values lower than 4 should certainly be avoided during processing as below this pH there appears to be a somewhat increased rate of hydrolysis of the carrageenan. This is in agreement with previous studies which also indicated that carrageenan hydrolysis was increased at pH below 4.0."²⁶

2. Inflammation and ulceration

In aiming to address the question of inflammation and ulceration, it is unclear why the TER does not discuss upfront the 2001 review article on this topic, authored by Tobacman and published in *Environmental Health Perspectives* (EHP). EHP is a publication of the federal government, published with support from the National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH), and the

²² Spichtig and Austin (2008), page 85.

²³ Spichtig and Austin (2008), page 85.

²⁴ Spichtig and Austin (2008), page 86.

²⁵ Stomach acid test, Medline Plus Medical Encyclopedia.

²⁶ Spichtig and Austin (2008), page 86

U.S. Department of Health and Human Services.²⁷

The EHP article reviewed 46 studies to explore this exact question posed by the Handling Subcommittee. Yet the TER first discusses individual studies, then briefly discusses the EHP review and concludes with criticism of the EHP article: "The article is critiqued by several industry-funded researchers who note that Tobacman's conclusions for carrageenan are inappropriately extrapolated from studies performed with poligeenan."²⁸ This criticism is unfounded. Tobacman's article notes whether degraded or undegraded carrageenan was used, and when this information is available, also notes the average molecular weight of carrageenan used in each of the studies included in the review.²⁹ The TER defines "poligeenan" as having a molecular weight of between 10-20 kDa; none of the studies included in Tobacman's review that used degraded carrageenan and specified the molecular weight have a molecular weight of 10-20 kDa. The criticism that the EHP review extrapolated from studies with poligeenan is therefore not based in fact.

It is also important to note that the 2001 EHP review included numerous studies that found adverse effects with undegraded carrageenan with a high molecular weight. Tobacman's review noted that multiple studies have shown harmful effects on the gastrointestinal system in association with exposure to degraded **and undegraded** carrageenan. Studies demonstrated significant ulceration of the cecum and/or large intestine after oral exposure to carrageenan in guinea pigs, rabbits, mice, rats and rhesus monkeys.³⁰

3. Tumor promotion and carcinogenicity

In this section of the TER, critically important studies are omitted. The first omitted study is Watanabe et al. (1978). In this study, researchers injected rats with a cancer initiator, and administered a diet containing 15% undegraded carrageenan to determine the effect of undegraded carrageenan in the diet on colon carcinogenesis.³¹ The molecular weight is not specified, only that the carrageenan is undegraded. The study was included in the 1983 IARC evaluation of carrageenan, which noted: "In female rats treated with azoxymethane or N-nitrosomethylurea together with native carrageenan in

²⁷ Environmental Health Perspectives, "Journal Information" (online at <http://ehp.niehs.nih.gov/journal-information>).

²⁸ Technical Evaluation Report. Compiled by OMRI for the USDA National Organic Program. February 10, 2016. line 166-167.

²⁹ Tobacman, J. (2001) Review of harmful gastrointestinal effects of carrageenan in animal experiments. Environmental Health Perspectives 109(10): 983-994. Page 986-989, Table 3.

³⁰ Tobacman, J. (2001) Review of harmful gastrointestinal effects of carrageenan in animal experiments. Environmental Health Perspectives 109(10): 983-994. Page 987.

³¹ Watanabe, K., Reddy, B. et al (1978) Effect of dietary undegraded carrageenan on colon carcinogenesis in F344 rats treated with azoxymethane or methylIntirosourea. Cancer Research 38: 4427-4430. Page 4427.

the diet, a greater incidence of colorectal cancers was observed than with treatment by azoxymethane or N-nitrosomethylurea alone."³²

The second study that was omitted from the TER is a 1986 study by Arakawa et al., in which researchers studied the effect of carrageenan on 1,2-dimethylhydrazine (DMH)-induced colonic tumors in rats. Unlike the 1978 Watanabe study, which administered a high-fat diet (20% fat) and high dose of carrageenan in the diet (15%), the 1986 Arakawa study administered a 6% fat diet and a lower dose of carrageenan (6%).³³ Results show that the number of tumors per rat was significantly higher in the group given DMH and the carrageenan diet compared to the group given DMH and the control diet. The size of the tumors in the group fed the carrageenan diet was also larger, with over half of the tumors larger than 5 mm (55% in the DMH+carrageenan group, compared with 27% of the tumors in the DMH group without carrageenan).³⁴

The third study omitted from the TER is a 1997 study by French scientists, who published the results of an experiment with rats that aimed to test their hypothesis that an aqueous jelly of undegraded carrageenan would not promote chemical carcinogenesis when given *after* the injections with the cancer initiator. Thirty rats were given a single injection of azoxymethane to initiate colon cancer, and then randomly allocated 7 days later to one of three groups for 100 days: a control group given pure water, a group given water supplemented with 0.25% (liquid) carrageenan or a group given water supplemented with 2.5% solid gel carrageenan. Results showed that "the administration of liquid 0.25% carrageenan reduced the number of aberrant crypt foci (ACF) per rat and did not change the ACF multiplicity compared to controls ($P=0.9$). By contrast, the administration of carrageenan jelly (2.5%) for 100 days promoted the growth of aberrant crypt foci ($P=0.016$)." The authors wrote that their hypothesis was not supported, and that "the long-term administration of a carrageenan jelly can enhance the intestinal tumor growth in rats."³⁵

The follow up to this study, Tache et al. (2000), is included in the TER. In this study, the researchers tested the hypothesis that human microflora have a protective effect, and the study has been used to disregard the findings of numerous animal studies showing cancer promoting effects of undegraded carrageenan. The researchers found that carrageenan did contribute to growth promotion of AOM-induced tumors in conventional

³² International Agency for Research on Cancer (IARC), Agents Classified by the IARC Monographs, Volumes 1-110. <http://monographs.iarc.fr/ENG/Classification/ClassificationsGroupOrder.pdf>. page 89.

³³ Arakawa, S., Okumura, 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 Vitamology* 32: 481-485. Page 482.

³⁴ Arakawa, S., Okumura, 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 Vitamology* 32: 481-485. page 483, table 2.

³⁵ Corpet, D.E., Tache, S. and M. Preclaire (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.

rats at the highest dose, but did not promote growth in any of the human-fecal-affiliated rats.³⁶ However, this study is poorly designed and does not control for various confounding variables. Most importantly, the control group should have been germ-free rats dosed with 1 mL rat fecal samples, similar to the germ-free rats that were dosed with 1 mL human fecal samples. As conducted, this experiment did not control for the fact that the treatment group was germ-free and living in a sterile environment. Therefore, the results cannot be used to conclude, as some have done, that results from animal studies showing cancer-promoting effects of undegraded carrageenan in the diet are not relevant to humans.

The multiple animal studies showing cancer promoting effects of carrageenan should not be dismissed. Researchers use animals in experiments to determine the health effects of materials, because experimentation on human beings to determine the carcinogenicity of materials is unethical. The NOSB should not dismiss these findings.

4. Insulin resistance and diabetes

In discussing the effects of insulin resistance and diabetes, the TER notes that animal studies with mice have indicated that carrageenan in the diet leads to insulin resistance³⁷ and therefore may contribute to the development of diabetes. It is also important to note that these studies use undegraded carrageenan, and that amount of carrageenan ingested in the mouse studies was less than anticipated in a typical Western diet.

Summary

Animal studies have shown ulcerative colitis-like disease and intestinal lesions and ulcerations in some animals. Degraded carrageenan (not "poligeenan") is classified by IARC as possibly carcinogenic to humans based on findings of its carcinogenicity in animal studies. Not even industry-funded studies have been able to show that carrageenan ingredients are reliably free from degraded carrageenan. Additional studies in animals have shown carrageenan may act as a promoter of colon tumors; three of these studies were not included in the 2016 Limited Scope TER on carrageenan. More recent research links carrageenan to insulin resistance and the development of Type 2 diabetes.

We opposed the relisting of carrageenan at the 2010 NOSB meeting and oppose it again at this meeting, given the research pointing to harmful health impacts. OFPA sets a high bar for food additives, requiring that **all** criteria be met, including impacts on human health. Given the research on carrageenan and health impacts, carrageenan should not be

³⁶ Tache, S., Peiffer, G. et al (2000) Carrageenan gel and aberrant crypt foci in the colon of conventional and human flora-associated rats. *Nutrition and Cancer* 37(2): 193-198.

³⁷ Bhattacharya, S., et al. (2012) "Exposure to the common food additive carrageenan leads to glucose intolerance, insulin resistance and inhibition of insulin signaling in HepG2 cells and C57BL/6J mice." *Diabetologia* 55:194-203.

allowed in organic food production. The relisting of carrageenan, given the scientific evidence of potential harm, would deal a serious blow to consumer trust in the integrity of the organic label.

Discussion Document: Phosphate Food Additives

We are pleased to see a discussion document by the Handling Subcommittee on the cumulative impact of phosphate food additives.

We pointed out in our Fall 2015 and Spring 2016 comments to the NOSB that recent research has shown that high intake of phosphorus is associated with negative impacts on bone health, kidney health and heart health.³⁸ 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 whole foods.³⁹

We agree with the Handling Subcommittee that it is difficult to implicate any individual phosphate food additive or food item; rather, it is the widespread use of phosphate food additives that gives rise to human health concerns.

Unlike carrageenan's sunset review, in which one particular food additive raises human health concerns and should be removed because it fails to meet the human health criterion in OFPA, we believe that phosphate food additives as a category fail to meet the human health criterion, and each individual phosphate food additive should therefore be reviewed on the basis of essentiality.

If a product can be made without a phosphate food additive, it is not essential. The prohibition on all phosphate food additives except monocalcium phosphate as a leavening agent in European, Japanese, Codex, and IFOAM standards demonstrates that phosphate food additives (with the possible exception of monocalcium phosphate as a leavening agent) are not essential.

We urge the NOSB to take the next step of putting the sunset review of phosphate food additives back on the agenda, in order to begin the process of removing all phosphate food additives from the National List, with the possible exception of monocalcium phosphate if it can be shown by organic food manufacturers that this ingredient is essential.

³⁸ Guterrez, 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.

³⁹ 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.

Nutrient Vitamins and Minerals

The Handling Subcommittee had a discussion document for public review prior to the Spring 2016 meeting, and gathered public comment on the best option for an annotation change. We are disappointed that the Handling Subcommittee does not have a proposal for an annotation change for the "nutrient vitamins and minerals" listing after gathering public comment, and that the issue of "nutrient vitamins and minerals" does not appear on the agenda.

The NOP has acknowledged in a public memo that its interpretation of the current listing for "nutrient vitamins and minerals," and its annotation referencing FDA regulations, is inappropriate.⁴⁰

The group listing for "nutrient vitamins and minerals" and its annotation referencing FDA regulations should be removed from the National List, and 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.

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, and considered essential.

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

205.605(a) non-synthetics allowed

Vitamins and minerals:

Calcium carbonate	<i>(Calcium)</i>
Calcium chloride	<i>(Calcium and Chloride)</i>
Calcium sulfate - mined	<i>(Calcium)</i>
Magnesium sulfate	<i>(Magnesium)</i>
Potassium chloride	<i>(Potassium and Chloride)</i>
Potassium iodide	<i>(Potassium and Iodine)</i>

205.605(b) synthetics allowed

Vitamins and minerals:

Acids (citric)	<i>(Vitamin C)</i>
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⁴⁰ National Organic Program. April 26, 2010. Action Memorandum for the Chairman of the National Organic Standards Board. Available at: <https://www.ams.usda.gov/sites/default/files/media/NOSB%20Memo%20Scope%20of%20Nutrient%20Vitamins%20and%20Minerals.pdf>

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)⁴¹

The following vitamins and minerals would need to be petitioned:

Vitamin A
Vitamin D
Vitamin B2 / Riboflavin
Vitamin B12

We urge the Handling Subcommittee to continue its work on this important issue.

Petition: Oat Protein Concentrate

We oppose the petition to add non-organic oat protein concentrate to the National List, and we support the Handling Subcommittee's unanimous decision to propose rejecting the petition.

Lack of organic oats in the proximity of a processing factory is not a reason to allow a non-organic ingredient in organic foods. Oat protein concentrate also fails the essentiality criterion, as organic foods can be made and processed without it.

Sunset Review: Beta Carotene Extract

⁴¹ 7 C.F.R. § 205.605.

We oppose the relisting of beta carotene extract on the National List. Color additives are not essential to making and processing organic foods, and organic colors are available.

Livestock Subcommittee

Antibiotic use in organic hatcheries

Antibiotics are prohibited in organic food production; however, the Organic Foods Production Act of 1990 allows for the use of antibiotics in chicks prior to day 2 of life because it exempts day-old chicks from organic management.⁴²

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. 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 are disappointed that the Livestock Subcommittee has not taken action on this issue. From the 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, we believe that 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 which would satisfy a key purpose of OFPA concerning consumer assurance and organic consistency as well as other mandatory labeling standards under separate acts.

We therefore do not believe that the OFPA exemption for day-old chicks from organic management prevents the NOSB from recommending a prohibition on all antibiotic use in organic poultry production.

For a full discussion and legal analysis of this approach, please see Appendix B.

Poultry Genetics

Since the Spring 2015 meeting, we have requested that the NOSB add the topic of poultry genetics to its workplan. We believe there is a need in the organic standards for a

⁴² 7 U.S.C. § 6509(e)(1).

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.⁴³

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.⁴⁴ Fast-growing birds also often suffer from acute heart failure and Sudden Death Syndrome.⁴⁵ 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.

Materials/GMO Subcommittee

Proposal: Fall 2016 Research Priorities

One of the Materials Subcommittee's (MS) requests for research involves "consumer demand." The MS writes, "How can the NOSB determine whether the consumers and groups who speak up are truly representing all consumers of organic," and that "research showing the distribution curve of consumer preference and expectations around organic products would be helpful."

For more than a decade, Consumers Union has provided credible survey information about consumer sentiment, based on nationally representative consumer survey data, on important issues to the NOSB. We have provided this data to the NOSB and will continue to do so.

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

⁴³ Knowles, T.G., Kestin, S.C. et al (2008) Leg disorders in broiler chickens: prevalence, risk factors and prevention. Plos One 2: e1545.

⁴⁴ Kalmar, I.D., Vanrompay, D. and Janssens, G.P. (2013) Broiler ascites syndrome: collateral damage from efficient feed to meat conversion. The Veterinary Journal 172(2): 169-174.

⁴⁵ Olkowski, A.A. (2007) Pathophysiology of heart failure in broiler chickens: structural, biochemical, and molecular characteristics. Poultry Science 86(5): 999-1005.

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 for the NOSB on consumer sentiment 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.

The NOSB should not base important materials review decisions on consumer buying habits. Our findings show that many purchasing decisions are likely the result of consumer confusion; for example, the overwhelming majority of U.S. consumers think that the organic label guarantees that the food is free from artificial materials.⁴⁶

We disagree with the argument — so often voiced during NOSB discussions — that the purchasing habits of U.S. consumers show consumer support of the use of artificial materials.

First, this argument is based on the assumption that consumers who purchase organic foods with artificial ingredients are aware of the use of artificial materials in organic food production. We now know, based on our nationally representative survey results, that this assumption is flawed. Nearly three-quarters of U.S. consumers who purchase organic foods do not know that artificial materials are allowed.⁴⁷ When they purchase organic foods with artificial ingredients, they are not signaling that the use of artificial ingredients is acceptable to them.

Second, our consumer survey data show that almost 9 out of 10 U.S. consumers state that they think that organic foods should be produced and processed without the use of artificial materials.⁴⁸

We are submitting, along with our comment, the full reports for four of our surveys (March 2014, June 2014, 2015 and 2016), and we urge the NOSB to use these data to inform its decisions. In addition to addressing the NOSB's question regarding the disconnect between consumer buying habits and expectations, the surveys also cover consumer expectations of antibiotic use in organic agriculture (day-old poultry), organic aquaculture standards, sunset review and other topics.

⁴⁶ Consumer Reports National Research Center, Natural Food Labels Survey: 2015 Nationally-Representative Phone Survey, Survey Research Report (Jan. 29, 2016) (online at www.consumerreports.org/content/dam/cro/magazine-articles/2016/March/Consumer_Reports_Natural_Food_Labels_Survey_2015.pdf).

⁴⁷ Id.

⁴⁸ Id.

Proposal: Excluded Methods Terminology

We strongly support the proposal for guidance on Excluded Methods Terminology and recommend that it be adopted by the NOSB. This guidance has three sections: Definitions, Principles and Criteria, and a Terminology Chart of excluded and allowed methods. We feel the definitions of “genetic engineering” (GE), “genetically modified organism” (GMO), “modern biotechnology,” “synthetic biology,” “non-GMO,” and “classical/traditional plant breeding” are all appropriate and very clearly defined. We believe that the overarching term “modern biotechnology,” developed by the Codex Alimentarius Commission (CAC), is the most important definition, since documents and standards developed by the CAC are referenced by the World Trade Organization in trade disputes involving food and they constitute a globally accepted standard. We believe the other definitions associated with “modern biotechnology,” such as GE, GMO, Non-GMO, and synthetic biology, all fall under the definition of modern biotechnology but are useful to define since those terms, especially GMO and non-GMO, are the terms most recognized by the public and used on labels. Finally, the definition of classical/traditional plant breeding is important to have spelled out since it has not been explicitly defined before.

The Principles and Criteria section is also appropriate because it makes clear that—since the organic regulations are a process-based system—it is appropriate that the excluded techniques should be process-based as well. We feel this section clearly explains how techniques are to be evaluated in determining whether they should be allowed in organic agriculture or not. Thus, as new techniques of breeding are developed, there is a rationale for how to determine whether they should be allowed or excluded.

Finally, we also support the Terminology Chart, which shows which techniques or terminologies (which are clearly defined in Appendix A) are excluded or allowed in organic production and the criteria that were used to make that determination. However, we believe that the four additional terms in the Discussion Document's Terminology Chart—transposon, cisgenesis, intragenesis and agro-infiltration—should also be considered excluded methods. We urge the NOSB to add these terms to the proposal's Terminology Chart before approving the proposal.

NOSB should recommend that the National Organic Program (NOP) and new administration codify the new guidance as regulations, which would provide legally binding clarity. Given the rapid introduction of food engineered via new genetic engineering techniques into the market, voluntary guidance alone could create a bottleneck of proposals for the NOSB to review, could create much confusion, and should be avoided. If there is concern about the timeline required for the adoption of regulations, the recommendations should be adopted as guidance while beginning the process of promulgating regulations.

Discussion Document: Excluded Methods Terminology

Four of the terms in the Terminology Chart—transposon, cisgenesis, intragenesis and agro-infiltration—should not be listed as TBD (to be determined), but should be considered excluded methods. We urge the NOSB to add these terms to the proposal's Terminology Chart as excluded methods before voting to approve the proposal.

Agro-infiltration, as the accompanying note in the chart notes, 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 so clearly falls under the definition of “modern biotechnology,” and should be an excluded technique since modern biotechnology is an excluded method.

Cisgenesis and intragenesis are also forms of genetic engineering and so, 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.”⁴⁹ 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.⁵⁰ Both cisgenesis and intragenesis are clearly subsets of genetic engineering and so clearly constitute an excluded method.

Transposons are mobile genetic elements that have been used to genetically engineer plants and animals.⁵¹ These uses clearly constitute an excluded method since they are used in genetic engineering. Transposons can also be used to create animals' vaccines. While GE vaccines are not prohibited in the organic program due to the exemption of vaccines from the excluded methods terminology, we feel that 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 fall 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 believe that the terms transposons, cisgenesis, intragenesis, and agro-infiltration should be listed as “excluded” in the Terminology Chart in the proposed guidance on Excluded Methods.

⁴⁹ Schouten HJ, Krens FA and E Jacobsen. 2006. Cisgenic plants are similar to traditionally bred plants. *EMBO Reports*, 7(8): 750-753. At:

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1525145/pdf/7400769.pdf>

⁵⁰ See slide 11 in <http://www.slideshare.net/HudaNazeer/transgenesis-intragenesis-cisgenesis>

⁵¹ Ivics Z and Z Izsvák. 2010. The expanding universe of transposon technologies for gene and cell engineering. *Mobile DNA*. At: <https://mobilednajournal.biomedcentral.com/articles/10.1186/1759-8753-1-25>

Crops Subcommittee

Proposal: Hydroponics

We urge the NOSB to vote at this meeting on whether to allow products of bioponics, including hydroponics, aeroponics, or aquaponics, to be labeled as organic—and to reject this proposal.

While hydroponics may have a place in our food system, we do not believe that the principles of hydroponic production align with the principles of organic food production. We are not opposed to hydroponic production *per se*, but we are opposed to products of hydroponic systems being labeled as “organic.”

One of the founding principles—arguably *the* founding principle—of organic agriculture is the focus on soil health to produce healthy crops and healthy animals, which in turn fosters the health of people.⁵² Living soil provides the basis for organic crop production, which relies on the recycling of nutrients, rather than on outside inputs for fertility and plant growth.⁵³ Hydroponic systems do not fit this model of food production; they do not “feed the plant by feeding the soil,” because there is no soil. It is because of this basic disconnect between the principles of organic production and the principles of hydroponic production means that we do not believe that products of hydroponic systems should be labeled as “organic.”

Appendices

Appendix A: Application of OFPA Criteria for National List Review

The Organic Foods Production Act of 1990 (OFPA) establishes as one of its fundamental standards for organic production a prohibition on the production and handling of agricultural products using synthetic chemicals, unless OFPA provides for an exception.⁵⁴ One of the main exceptions to this “no synthetics in organic” standard found within OFPA is the mandate to create the National List, which consists of substances that would otherwise be prohibited or allowed under the general organic standards.⁵⁵ OFPA and its drafters, however, merely established a National List and its criteria, leaving the precise determination of what substances could and could not be included on that list to the discretion of the Secretary, the organic industry, or even the public.

⁵² See IFOAM Principles of Organic Agriculture, <http://www.ifoam.bio/en/principles-organic-agriculture/principle-health>

⁵³ See IFOAP Principles of Organic Agriculture, <http://www.ifoam.bio/en/principles-organic-agriculture/principle-ecology>

⁵⁴ 7 U.S.C. § 6504(1).

⁵⁵ 7 U.S.C. § 6517(a) – (c).

Instead, OFPA lays out mandatory criteria that each and every substance on the National List, whether used in organic farming or handling, must be evaluated against before being added to the list. The criteria includes:

(1) Exemption for prohibited substances in organic production and handling operations

The National List may provide for the use of substances in an organic farming or handling operation that are otherwise prohibited under this chapter **only if**—

(A) the Secretary determines, in consultation with the Secretary of Health and Human Services and the Administrator of the Environmental Protection Agency, that the use of such substances—

- (i) would not be harmful to human health or the environment;
- (ii) is necessary to the production or handling of the agricultural product because of the unavailability of wholly natural substitute products; **and**
- (iii) is consistent with organic farming and handling;⁵⁶

OFPA takes additional steps beyond these criteria and establishes mandatory procedures that must be utilized in developing the National List, which includes the requirement that the Secretary base the National List on the proposed National List or proposed amendments to the National List provided by the NOSB.⁵⁷ In turn, OFPA directs the NOSB to develop its proposed National List or amendments according to all provisions within section 6517—the National List section of the Act, which incorporates the above-noted criteria.⁵⁸ It is also within this section that an automatic expiration date of five years for every substance added to the National List, known as sunset, is also mandated.⁵⁹ Through this detailed framework, OFPA ensures that exceptions to the organic rule are scrutinized to the highest degree.

It is not only the fundamental “no synthetics” organic standard that consumers depend on each time they reach for products labeled “organic,” but also this heightened scrutiny of exceptions to the organic standard. This is why when the Consumer Reports National Research Center conducted a survey on organic food labels, 71% of consumers

⁵⁶ 7 U.S.C. § 6517(c)(1)(A) (emphasis added).

⁵⁷ 7 U.S.C. § 6517 (d)(1).

⁵⁸ 7 U.S.C. § 6518 (k)(2).

⁵⁹ 7 U.S.C. § 6517((1)(C) (“The National List may provide for the use of substances in an organic farming or handling operation that are otherwise prohibited under this chapter only if—(C) the specific exemption is developed using the procedures described in subsection (d) of this section.”); 7 U.S.C. § 6518; 7 U.S.C. § 6517(e).

polled wanted approval for *as few* artificial ingredients as possible and 84% thought that the use of artificial ingredients in organic products should be discontinued, if not reviewed, after 5 years.⁶⁰

Indeed, from the beginning drafters of OFPA were keenly aware of consumer expectations concerning organic and did not intend for exceptions to the organic rule to be abused or expansively interpreted:

Most consumers believe that absolutely no synthetic substances are used in organic production. For the most part, they are correct and this is the basic tenet of this legislation. But there are a few limited exceptions to the no-synthetic rule and the National List is designed to handle these exceptions.

...

The Committee does not intend to allow the use of many synthetic substances. This legislation has been carefully written to prevent widespread exceptions or ‘loopholes’ in the organic standards which would circumvent the intent of the legislation.⁶¹

Yet, on several fronts, the application of the fundamental organic “no synthetic” principle and underlying “restricted exceptions” concept on which consumers rely has strayed significantly from OFPA’s clearly-defined standards and drafters’ intentions, and one of these fronts is in the review of National List criteria.

Consumer Reports has submitted dozens of comments over the last 15 years on both materials petitioned to and those already on the National List. The review process has been inconsistent and in some cases inadequate. Overall, we wish to remind the NOSB of three important overarching points with regard to upholding OFPA’s standards and applying the mandatory National List criteria and procedures and encourage the NOSB to consider these points in conducting its important responsibilities.

1. Each and every substance on the National List is required to consistently meet ALL of the National List criteria—one should not be prioritized over another.

We recognize that even with clearly defined National List criteria at both the statutory and regulatory levels, evaluating individual substances according to those criteria is not always black and white and requires a complex balancing of factors. Yet, too often, in actuality, one mandatory criterion has usurped another mandatory criteria

⁶⁰ Consumer Reports National Research Center, *Organic Food Labels Survey: 2014 Nationally-Representative Phone Survey* 1,016 adult U.S. Residents, March 2014, p. 2, available at <http://greenerchoices.org/wp-content/uploads/2016/08/CR2014OrganicFoodLabelsSurvey.pdf>

⁶¹ U.S. Senate, Committee on Agriculture, Nutrition, and Forestry, Food, Agriculture, Conservation, and Trade Act of 1990, July 6, 1990, Report 101-357, p. 298.

completely, undermining the integrity of organic and consistency on which consumers rely and OFPA guarantees.

In most cases, it is the second criterion, which states that a substance can be added to the National List only if it is “necessary to the production or handling of the agricultural product because of the unavailability of wholly natural substitute products,” in which we have seen the greatest overemphasis even when harmful health and environmental impacts and/or inconsistency with organic farming and handling is well documented.

Part of this inconsistent application of OFPA criteria stems from not only the failure to apply ALL of the National List criteria with equal weight and importance, but also in the failure to interpret each criteria with an eye to the plain language of the provision and context of the whole of the statute. This is in part why the three criteria exist and must all be met.

Regardless of whether the substance is considered for livestock, handling, or crops, emphasis must be placed on all of the criteria and each of those criteria must be interpreted accurately and in the context of preserving organic integrity.

2. Regulations provide additional National List criteria and considerations, not alternatives to OFPA National List criteria.

To make the job of the NOSB even more complex, giving proper weight and interpretive context to each mandatory National List criteria does not end with the text of OFPA. USDA regulations offer additional criteria and interpretation that also must be taken into consideration when evaluating National List materials; however, these regulations cannot be read in a vacuum or as an alternative to the law. At all times, OFPA regulations must be applied and interpreted so that they do not conflict with the statute and carry out the intentions of the drafters of that statute. This is what consumers expect and deserve.

The recurring disconnect from OFPA’s overarching National List criteria when evaluating substances to be included on section 205.606 of the National List (nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic”) offers an example. Section 205.606 states in its introductory text that, “Only the following non-organically produced agricultural products may be used as ingredients in or on processed products labeled as ‘organic,’ only in accordance with any restrictions specified in this section, and only when the product is not commercially available in organic form.”⁶²

⁶² 7 C.F.R. § 205.606.

There is no question that section 205.606 and the products it contains are a part of the National List. Thus all mandatory evaluation criteria as discussed above must apply to reviews of products considered for inclusion on the National List under this provision. But beyond this general mandatory criteria, the introductory paragraph of section 205.606 establishes the additional, not separate or alternative, criteria of assessing commercial availability for section 205.606 items.

Indeed, this is the very conclusion that the First Circuit reached when asked to weigh in on how section 205.606 must be interpreted in order to align with OFPA and its standards.⁶³ The First Circuit did not find section 205.606 to be in conflict with OFPA as long as it was interpreted as simply adding a further limitation on the addition of new nonorganic ingredients to the National List.⁶⁴ The Court also clarified that “this portion of the Rule may not be interpreted in a way that contravenes the National List requirements of OFPA,” and remanded the case to the District Court “for entry of a declaratory judgment that § 205.606 does not establish a blanket exemption to the National List requirements for nonorganic agricultural products that are not commercially available.”⁶⁵

Following this decision and a subsequent order from the District Court carrying out the directive of the Circuit Court, the NOP took steps to amend section 205.606 to emphasize the section’s inclusion in the National List’s statutory and regulatory regime, leading to the existing introductory paragraph.⁶⁶ Around the same time, the NOSB also took steps to clarify its recommendations concerning evaluation of the additional commercial availability criteria.⁶⁷

Despite the clear directive of the courts and NOSB efforts to assist in providing better guidance concerning evaluation of commercial availability, the practice of reviewing products for inclusion on the National List under section 205.606 and even the rules concerning what to include in a petition for inclusion have focused almost exclusively on evaluating commercial availability.⁶⁸ Moreover, perhaps because of the failure to apply the basic requirements of OFPA to every 205.606 substance review, the

⁶³ Harvey v. Veneman, 396 F.3d 28, 35-36 (1st Cir. 2005).

⁶⁴ *Id.*

⁶⁵ *Id.* at 36.

⁶⁶ U.S. Dept. of Agriculture, 71 Fed. Reg. 32803, *National Organic Program--Revisions to Livestock Standards Based on Court Order (Harvey v. Johanns) and 2005 Amendment to the Organic Foods Production Act of 1990, (OFPA)*, June 7, 2006, available at <http://www.gpo.gov/fdsys/pkg/FR-2006-06-07/html/06-5203.htm>.

⁶⁷ National Organic Standards Board, Formal Recommendation by the National Organic Standards Board (NOSB) to the National Organic Program (NOP), *Commercial Availability Criteria*, May 22, 2006, available at <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRD3456144>.

⁶⁸ National Organic Program--Submission of Petitions of Substances for Inclusion on or Removal From the National List of Substances Allowed and Prohibited in Organic Production and Handling, <http://www.regulations.gov/#!documentDetail;D=AMS-TM-06-0223-0001>.

commercial availability analysis has also become increasingly emphasized over fundamental organic standards and limited exceptions on which the law and consumers demand, leading to inclusion of substances like inulin,⁶⁹ with little to any application of basic OFPA criteria. In fact, transcripts show that materials such as inulin were specifically argued to be part of section 205.606 so that “essentialness” criteria would not apply.

Regulations, be it section 205.606 or other provisions of the OFPA Rule, are not an alternative to a statute’s requirements. As the gatekeeper of the National List, the NOSB must ensure that each exception to the organic standard receives the heightened scrutiny consumers expect.

3. National List procedures must be followed and those include consideration of all National List criteria at all stages of review—including sunset.

The final National List criteria point we ask the NOSB to consider is that exceptions to organic found on the National List are not meant to continue for eternity or even until someone makes a case to remove them. In fact, as noted earlier, it is a critical part of the limited exceptions framework envisioned by the drafters that each substance once on the National List receives an automatic expiration date of five years, after which the NOSB must review the substance according to the very same National List standards it considered when including the substance on the list.⁷⁰

Understanding that many of the OFPA standards concerning the review of materials at sunset have been flipped on their heads after the NOP’s promulgation of its September 16, 2013 Sunset Notice (NOP Sunset Notice), an issue we discuss more fully below, there should be no mistake that OFPA explicitly requires that the NOSB’s review at sunset be conducted “as provided in this section” and that section incorporates the National List criteria and procedures for review.⁷¹

Regardless of the confusion surrounding the NOP’s reversal of the vote to be taken by the full NOSB on sunset materials or the subcommittee’s role in precipitating that vote, there is no question that sunset materials must still be reviewed to evaluate their continuing compliance with the OFPA criteria.⁷² For each sunset material, the NOSB

⁶⁹ National Organic Standards Board, *NOSB Committee Recommendation*, Inulin OFS, March 2007, available at <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5058109>.

⁷⁰ 7 U.S.C. § 6517(e) (“No exemption or prohibition contained in the National List shall be valid unless the National Organic Standards Board has reviewed such exemption or prohibition *as provided in this section* within 5 years of such exemption or prohibition being adopted or reviewed and the Secretary has renewed such exemption or prohibition.”) (emphasis added).

⁷¹ *Id.*

⁷² “For substances that continue to meet the criteria for substances on the National List, the Subcommittee will summarize relevant information regarding its review of this substance.” U.S. Dept. of Agriculture, Notification of Sunset Process, 78 Fed. Reg. 56811, 56814, Sept. 16, 2013, available at <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5105103>.

should be reminding the public of the criteria that the material must be reviewed against and then clearly communicating its findings with regard to those criteria.

A substance's inclusion on the National List does not make it organic but grants a temporary exemption to organic standards. It allows the substance to be used under limited circumstances in the production or handling of organic products for a temporary period of time. Even with these limited allowances, consumer expectations are that synthetic and non-organic ingredients should not be a part of organic and that if an exception is made, the ingredient should be reviewed or done away with in a finite amount of time. Again, we point to our survey data to emphasize this point, in which an overwhelming majority (84%) of consumers think the use of artificial ingredients in organic products should be discontinued, if not reviewed, after 5 years; few consumers (15%) endorse continued use of the artificial ingredient without review.⁷³

In many instances the NOSB has diligently reviewed exceptions to the organic standards according to all the mandatory criteria and regulations and has done this at every step of the process. For these efforts, we applaud the Board, and ask for consumers' sake that it ensure this be the standard, as it was intended, for all National List materials.

Appendix B: Consumers Union's recommended approach to prohibiting antibiotics in day-old chicks and hatcheries

Consumers Union recognizes the OFPA limitation concerning day-old poultry; however, we would like to provide some additional background and analysis to aid the NOP and USDA in reconsidering all of the potential regulatory options available to them in addressing this problematic inconsistency within the organic label.

OFPA and Regulations

A. OFPA and the Day-Old Poultry Exemption

The provision within OFPA that exempts up to day-old poultry from organic production standards is found in section 6509(e) as codified. This section governs organic animal production practices and materials and reads as follows:

(e) Additional guidelines

(1) Poultry

With the exception of day old poultry, all poultry from which meat or eggs will be sold or labeled as organically produced shall be raised and handled in

⁷³ Consumer Reports National Research Center, *Organic Food Labels Survey: 2014 Nationally-Representative Phone Survey* 1,016 adult U.S. Residents, March 2014, p. 2, available at <http://www.fsis.usda.gov/wps/wcm/connect/6122594c-93db-46db-beb6-dc250bc43b6d/Petition-Consumers-Union-062614.pdf?MOD=AJPERES> at 10.

accordance with this chapter prior to and during the period in which such meat or eggs are sold.⁷⁴

In other words, all poultry that is to be labeled and sold as organic must be raised and handled in accordance with the organic standards established under OFPA and its implementing regulations, unless it falls within the day-old poultry time period. What this means is that day-old and younger poultry can be obtained from conventional hatcheries that have not been produced according to organic standards. Second-day and older poultry, however, cannot be sourced conventionally. OFPA regulations do not elaborate on the day-old poultry exemption.

B. OFPA and Antibiotics in Livestock

OFPA and its implementing regulations do address the use of antibiotics in livestock, by placing a general prohibition on any subtherapeutic treatment of livestock with antibiotics,⁷⁵ as well as use as a growth stimulant in feed.⁷⁶ These references are the only specific mention of antibiotics or medications within OFPA concerning livestock.

OFPA only prohibits treatment of animals with medications in the absence of illness⁷⁷ and OFPA regulations go one step further as to actually require treatment of sick animals for animal welfare purposes.⁷⁸ Because an antibiotic is considered a synthetic substance, however, and prohibited under organic production unless included on the National List, use of antibiotics on sick animals removes their organic eligibility in the marketplace and the resulting product cannot be labeled organic.⁷⁹ Treatment of a sick animal with an antibiotic, however, does not require that a livestock producer's organic certification as a whole be removed.

Additional Antibiotic Use and Labeling Standards

As you are aware, the power of the USDA as a whole to regulate labeling claims and consider consumer expectations with regard to those claims on certain food items is not limited to the confines of OFPA. In fact, to ensure that animal product labels are truthful, accurate, and not misleading to consumers—as required by USDA law and regulations—these claims must be submitted to the USDA's Food Safety and Inspection Service (FSIS) for approval prior to marketing in interstate commerce.⁸⁰ Moreover,

⁷⁴ 7 U.S.C. § 6509(e)(1).

⁷⁵ 7 U.S.C. § 6509(d)(1)(A).

⁷⁶ 7 U.S.C. § 6509(c)(3), *see also* 7 C.F.R. § 205.237(b)(7).

⁷⁷ 7 U.S.C. § 6509(d)(1)(C).

⁷⁸ 7 C.F.R. § 205.238(c)(7).

⁷⁹ *See* 7 C.F.R. § 205.60 *and* 7 C.F.R. § 205.238(c)(7) (“Livestock treated with a prohibited substance must be clearly identified and shall not be sold, labeled, or represented as organically produced.”).

⁸⁰ *See* 21 U.S.C. § 607(e); 21 U.S.C. § 457(c). *See also* accompanying regulations for meat and poultry inspections at 9 C.F.R. §§ 412.1 – 412.2.

while the organic label is primarily regulated within the confines of its own program and FSIS defers to the Agricultural Marketing Service (AMS) and NOP on approval and oversight of products carrying the organic label, it is still considered a label which falls under the purview and authority of FSIS's meat and poultry labeling responsibilities.⁸¹

While there is no regulation that details USDA positions or standards on claims involving "raised without antibiotics," "no antibiotics added," and similar statements, the USDA provides guidance on the process for label evaluations and general standards underlying it.⁸²

The USDA has made it known through individual label approvals, statements to Consumer Reports, and litigation concerning antibiotic statements on labels that the use of feed containing antibiotics, as well as the injection of hatchery eggs and day-old poultry with antibiotics, disqualifies a food from bearing a claim of "raised without antibiotics."⁸³ This has been confirmed through industry practice and statements to the media.⁸⁴

Options to Address the Organic Poultry and Egg Labeling Inconsistency

While understanding that the NOP and USDA must not violate OFPA, the Department as a whole must also be wary of violating explicit directives in separate sections of OFPA and in other statutes. In this case, we believe that OFPA requires the Department to assure consumers that organically produced products meet consistent standards⁸⁵ and that the Federal Meat Inspection Act (FMIA), Poultry Product Inspection

⁸¹ See U.S. Dept. of Agriculture, Food Safety Inspection Service, *Meat and Poultry Labeling Terms*, webpage available at http://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/food-labeling/meat-and-poultry-labeling-terms/meat-and-poultry-labeling-terms!/ut/p/a1/jZDNCsIwEISfxQcI2doqepSCtFVbRNSYi6ya1kCbIcYq-vRaREHxp7unZb5hh6GcMsoVHmWGVmqFeX3z7hqm0HX6PkRJ3xICGC-mycj3oTfr3IDVDyB2G_q_zAD--aMGD9rVxJ9klJdo90SqVFOWCUtQmZOoDGWp1jtiMBX2TFLcWmL2QtiHkONG5FJlIBUCa9eOIPqQ2-r8IIgVVWH-A0vKX-OCc9swdmdeEMUuJN478KHPO_C9sLKYs8t4EIAMW1dofMrM/#14.

⁸² See U.S. Dept. of Agriculture, A Guide to Federal Food Labeling Requirements for Meat Poultry, and Egg Products, available at http://www.fsis.usda.gov/shared/PDF/Labeling_Requirements_Guide.pdf; U.S. Dept. of Agriculture, Animal Production Claims Outline of Current Process, available at <http://www.fsis.usda.gov/wps/wcm/connect/6fe3cd56-6809-4239-b7a2-bccb82a30588/RaisingClaims.pdf?MOD=AJPERES>.

⁸³ *Sanderson Farms, Inc. v. Tyson Foods*, 547 F. Supp. 2d 491 (D.Md. 2008)(holding that Tysons "raised without antibiotics" campaign misled consumers when poultry was fed with ionophores and hatchery eggs injected with antibiotics two-to-three days before hatching.)

⁸⁴ See, e.g., Tom Philpott, Wait, We Inject Antibiotics Into Eggs for Organic Chicken?!, *MotherJones*, Jan. 15, 2014 ("Perdue has over the past five years removed antibiotics from 80 percent of its hatcheries[.]") available at <http://www.motherjones.com/tom-philpott/2014/01/organic-chicken-and-egg-antibiotics-edition>.

⁸⁵ 7 U.S.C. § 6501(2).

Act (PPIA), and Egg Products Inspection Act (EPIA) all prohibit the labeling of products that are misleading to consumers and thus misbranded.⁸⁶

Therefore, while the NOP faces a particular legal obstacle in the OFPA provision specifically exempting day-old poultry from organic standards (including the general prohibition of subtherapeutic antibiotic treatments) the canon of statutory interpretation and legal precedent require that all statutory language should be given effect unless leading to the truly absurd.

With this in mind, we would posit that 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 the full organic standards cannot be required for day-old poultry as a whole. Prohibiting the injection of eggs and day-old poultry with antibiotics does not amount to a requirement that these products adhere to organic production standards across the board, but rather a singular component. Furthermore, because implementing this singular requirement would be satisfying a key purpose of OFPA concerning consumer assurance and organic consistency as well as other mandatory labeling standards under separate acts, there is a strong argument that a narrowly tailored regulation addressing this issue would be viewed as legally favorable.

⁸⁶ 21 U.S.C. § 607(e); 21 U.S.C. § 457(c); 21 U.S.C. § 1036.