

**Consumer Reports Comments**  
To the National Organic Standards Board  
Spring 2015

April 7, 2015

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

Re: National Organic Standards Board Spring 2015 Meeting – Docket No. AMS-  
NOP-15-0002-0001

Thank you for the opportunity to submit comments on proposals and discussion documents posted for the Spring 2015 meeting of the National Organic Standards Board. These comments were prepared by Consumers Reports' Food Safety and Sustainability Center.

Consumer Reports is the world's largest independent product-testing organization. Using its more than 50 labs, auto test center, and survey research center, the nonprofit rates thousands of products and services annually. Founded in 1936, Consumer Reports has over 8 million subscribers to its magazine, Website and other publications. Its advocacy division, Consumers Union, works for health reform, food and product safety, financial reform, and other consumer issues in Washington, D.C., the states, and in the marketplace.

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

In this comment, we summarize the points that we believe to be important to consumers concerning the organic label and that we wish to emphasize during this NOSB meeting. We begin our comments with a general organic policy comments section, which applies to all subcommittee considerations and NOSB activities and should be read and applied

to all issue and substance discussions. The remaining sections of the comments are divided by subcommittee and address individual proposals, substances, and issues raised by each subcommittee. For ease of reference we are providing you with a Table of Contents:

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# GENERAL ORGANIC POLICY ISSUES

## Consumer Reports Surveys

Consumer Reports has provided survey data about consumer sentiment on important issues to the NOSB for more than a decade. In 2014, we conducted two nationally representative surveys to measure consumer expectations about the organic label.

We collaborated with 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 like the rest of Consumer Reports, it is free from corporate influence. National Research Center surveys are designed to gather unbiased, objective information from consumers akin to many independent national polls.

We surveyed 1,016 consumers in March 2014 and 1,004 consumers in April 2014. Our nationally-representative surveys included questions designed to understand what consumers think the organic label *should* mean. We believe these survey results provide an appropriate and sound measure of consumer expectations.

Our results show that 89% of U.S. consumers think that the “organic” label on processed foods should mean that the food is free from artificial ingredients, and 91% think it should mean no artificial materials were used.

While we understand that organic allows for exceptional use of artificial ingredients, we also believe that the NOP should understand this disconnect and ensure that exceptions are made carefully, with full review to ensure all OFPA criteria are met. Exceptions also should sunset after five years. Materials that remain on the National List well beyond the 5 year sunset period are simply not in line with consumer expectations. We hope that the NOSB will use the findings of these surveys to inform its votes and decisions.

We raise the following general organic policy issues to outline some of our overarching concerns where consumer expectations and organic do not align.

## Application of OFPA Standards and National List Criteria

The Organic Foods Production Act (OFPA) establishes as one 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.<sup>1</sup> 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

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<sup>1</sup> 7 U.S.C. § 6504(1).

prohibited or allowed under the general organic standards.<sup>2</sup> OFPA and its drafters, however, did not stop with the edict to develop a National List, leaving the 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.

Instead, OFPA lays out mandatory criteria that each and every substance, whether used in organic farming or handling, on the National List 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**—

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; . . . .<sup>3</sup>

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.<sup>4</sup> 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.<sup>5</sup> It is also within this section that an automatic expiration date of five years

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<sup>2</sup> 7 U.S.C. § 6517(a) – (c).

<sup>3</sup> 7 U.S.C. § 6517(c)(1)(A) (emphasis added).

<sup>4</sup> 7 U.S.C. § 6517 (d)(1).

<sup>5</sup> 7 U.S.C. § 6518 (k)(2).

for every substance added to the National List, known as sunset, is also mandated.<sup>6</sup> 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 that green and white circle, but also this heightened scrutiny of exceptions to the organic standard. This is why when Consumers Reports National Research Center conducted a survey on organic food labels, 71% of consumers polled want approval for *as few* artificial ingredients as possible and 84% think that the use of artificial ingredients in organic products should be discontinued, if not reviewed, after 5 years.<sup>7</sup>

Indeed, from the beginning drafters of OFPA were keenly aware of consumers 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.<sup>8</sup>

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.

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<sup>6</sup> 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).

<sup>7</sup> 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.greenerchoices.org/pdf/CR2014OrganicFoodLabelsSurvey.pdf>.

<sup>8</sup> 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.

Consumer Reports has submitted dozens of comments over the last 15 years on materials petitioned and on the National List. The review process has been inconsistent and in some cases inadequate. Throughout these comments Consumers Reports will address individual instances of where National List criteria and procedures have faltered, as well as where these standards have been applied and upheld through thorough, transparent, and well-executed review. Overall, however, 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 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.**

Consumer Reports recognizes 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 criterion 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,” where we have seen the greatest over-emphasis even when harmful health and environmental impacts and/or inconsistency with organic farming and handling is well-documented.

Methionine offers a prime example. In both the NOSB recommendations concerning synthetic methionine’s use in poultry feed and its use in soy-based infant formula,<sup>9</sup> harm to the environment and inconsistency with organic production principles were clearly identified.<sup>10</sup> Additionally, in both cases, several wholly natural sources of synthetic methionine were identified, but were dismissed as “commercially unavailable,” leading the NOSB and Livestock Committee to recommend methionine’s inclusion on the National List.

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<sup>9</sup> National Organic Standards Board, Formal Recommendation, *Petition to add L-Methionine to the National List at §205.605*, Oct. 17, 2012, <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5101289>.

<sup>10</sup> National Organic Standards Board, Formal Recommendation, *Petition to add L-Methionine to the National List at §205.605*, Oct. 17, 2012, <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5101289> and National Organic Standards Board, Formal Recommendation by the National Organic Standards Board (NOSB) to the National Organic Program (NOP), *Renewal of DL-Methionine on National List until October 1, 2008*, March 18, 2005, available at <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5058112>.

Recognizing that the full-effect of the soy-based formula recommendation remains in limbo due to the National Organic Program (NOP)'s delay in addressing a final rule on nutrient vitamin and minerals and that Food and Drug Administration requires methionine be added to soy-based formulas,<sup>11</sup> it is worth noting the NOSB's "balancing" of criteria in reaching its determination as to whether to include the substance on the National List and thus allow in organically-labeled products:

A number of soy-based baby formulas are supplemented with L-methionine because soy formula (unlike milk-based formula or breast milk) does not provide adequate levels of methionine to ensure adequate growth, nitrogen balance, and plasma albumin concentrations. Therefore L-Methionine is required in soy based infant formulas in order to meet FDA requirements for protein quality at 21 CFR 107.100 (f). The Handling subcommittee recommends approval, acknowledging the fact that if L-Methionine is not added to soy formula there would be no organic soy based formula.<sup>12</sup>

Similarly, the NOSB since its first recommendation to include synthetic methionine on the National List for poultry feed in 2001 has noted the substance was not consistent with organic agriculture<sup>13</sup> and identified harmful environmental impacts from methionine's production.<sup>14</sup> Thus in both cases, two of the three mandatory National List criteria, harmful environmental impacts and inconsistency with organic farming and handling, were unsatisfied. While acknowledging these deficiencies in meeting the National List criteria, the NOSB still proceeded in recommending that it be listed—contrary to explicit OFPA requirements, the drafters intentions, and consumers expectations.

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 the plain language of the provision and

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<sup>11</sup> U.S. Dept. of Agriculture, *National Organic Program (NOP); Sunset Review (2012) for Nutrient Vitamins and Minerals*, 77 Fed. Reg. 59287, Sept. 27, 2012, available at <http://www.regulations.gov/#!documentDetail;D=AMS-NOP-10-0083-0029>; see also 21 CFR 107.100 (f).

<sup>12</sup> National Organic Standards Board, Formal Recommendation, *Petition to add L-Methionine to the National List at §205.605*, Oct. 17, 2012, p. 2, available at <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5101289>.

<sup>13</sup> U.S. Dept. of Agriculture, SUMMARY OF NOSB ACTIONS OCTOBER 15-17, 2001 WASHINGTON, DC, available at <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5057497>.

<sup>14</sup> See National Organic Standards Board Technical Advisory Panel Review for the USDA National Organic Program, Methionine Livestock, May 21, 2001, available at <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5067079&acct=nopgeninfo> and Technical Evaluation Report Compiled by ICF International for the USDA National Organic Program, Methionine Livestock, Nov. 15, 2011, available at <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5098033>.

context of the whole of the statute. This is in part why the three criteria exist and must all be met for you cannot determine necessity without also considering consistency with organic production and potential harm to the environment and health.

Again looking at the second criterion and the example of synthetic methionine, we have seen of the plain language of the provisions—applying interpretations of “necessity” or essentiality with an exclusive focus on “unavailability of wholly natural substitute products” and little regard to the organic context or the fact that this is not the same as “commercial availability.” Ironically, neither “essentiality” nor “necessity” is defined by statute or regulations, yet “commercial availability” is defined. The result in many instances has been to replace or confuse the “necessary to production” and “wholly natural availability” components of the second criteria with “commercial availability.”

Refusing to list synthetic methionine may mean there can be no organic soy-based formula, but is soy-based formula necessary to organic production? It is consistent with organic when wholly natural substitutes for methionine are used. This is not denying the market of soy-based formula or even denying babies a critical amino acid, but rather communicating honestly with consumers that soy-based formula with *synthetic* methionine is not consistent with the standards they associate with organic. These same arguments apply to the use of methionine in poultry production and we refer you to our Livestock Subcommittee comments for a more in depth discussion on this issue in the poultry context.

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. United States Department of Agriculture (USDA) regulations offer additional criteria and interpretation that must also 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 paragraph 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.”<sup>15</sup>

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 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.<sup>16</sup> 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.<sup>17</sup> 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.”<sup>18</sup>

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.<sup>19</sup> Around the same time, the NOSB also took steps to clarify its recommendations concerning evaluation of the additional commercial availability criteria.<sup>20</sup>

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<sup>15</sup> 7 C.F.R. § 205.606.

<sup>16</sup> *Harvey v. Veneman*, 396 F.3d 28, 35-36 (1<sup>st</sup> Cir. 2005).

<sup>17</sup> *Id.*

<sup>18</sup> *Id.* at 36.

<sup>19</sup> 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>.

<sup>20</sup> 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>.

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.<sup>21</sup> And perhaps because of the failure to apply the basic requirements of OFPA to every 205.606 substance review, the 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<sup>22</sup> with little to any application of basic OFPA criteria. In fact, transcripts show that materials such as inulin were specifically argued to be 606 so that “essentialness” criteria would not apply.

Consumer Reports supports the extensive comments provided by the National Organic Coalition (NOC) on section 205.606 and commercial availability and we encourage the NOSB to review the thoughtful suggestions for improving commercial availability analysis and better aligning it with general organic principles, which include continual development and improvement of organically sound products and production practices.

But in addition to NOC’s comments, Consumers Reports believes it is important to emphasize the that OFPA procedures for establishing the National List explicitly require NOSB review and recommendation and the NOSB in carrying out that mandatory duty must do it in accordance with all of the National List criteria and procedures. We refer you to our comments on 205.606 sunset materials below to see where we believe this criteria is not being met for individual substances.

Regulations, be it 205.606 or other provisions of the OFPA Rule, are not an alternative to 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

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<sup>21</sup> 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>.

<sup>22</sup> National Organic Standards Board, *NOSB Committee Recommendation, Inulin* OFS, March 2007, available at <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5058109>.

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.<sup>23</sup>

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.<sup>24</sup>

Yet for some of the substances listed in the Spring 2015 NOSB Report, there is a failure to integrate the National List criteria in making the subcommittee proposals for 2016 sunset materials. For example, the Crops Subcommittee did not apply the concise OFPA criteria checklists to its sunset proposals for ferric phosphate and hydrogen chloride or even provide a summary evaluation of whether each OFPA criteria was satisfied. Instead, the subcommittee provided vague points "in favor of renewing substance" and "against renewing substance." While some of these points mentioned OFPA criteria like essentiality, it offered little insight into whether the substance continued to meet ALL of the mandatory OFPA criteria. We believe that the NOSB should explicitly document how all OFPA and NOP criteria are met for each substance that is petitioned or re-listed.

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.<sup>25</sup> For each sunset material, the NOSB 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. It allows the substance to be used under limited circumstances in the production or handling of organic products for a temporary period of

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<sup>23</sup> 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).

<sup>24</sup> *Id.*

<sup>25</sup> "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>.

time. Even with these limited allowances, consumer expectation is that synthetic and artificial 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, where 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.<sup>26</sup>

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

## Sunset

The National Organic Program's changes to the sunset review process and standards, mandated by its September 16, 2013 federal register notice, continue to be a significant concern to Consumers Reports with regard to undermining organic integrity and consumers' expectations for organic. Last year, we downgraded the rating of the "organic" label from "highly meaningful" to "meaningful" in part because of this serious undermining.<sup>27</sup>

Despite repeated calls from the organic community to subject the NOP Sunset Notice to public notice and comment and correct several provisions of the NOP Sunset Notice to reflect OFPA's requirements, the NOP has remained persistent in its effort to enforce its misguided sunset standards and procedures. From the most egregious violations, such as changing the vote of the NOSB from two-thirds to renew a material's inclusion on the National List to one requiring two-thirds to remove it, to prohibiting annotations to listing at sunset, the result continues to be a convoluted sunset review that fails to subject exceptions to organic to repeated and necessary scrutiny required under OFPA. The NOP has made it easier to maintain the use of synthetic, otherwise-prohibited material in organic production and to minimize the incentive to create organic alternatives. This is a serious undermining of the integrity of the organic label.

Consumer Reports acknowledges that the NOSB has little control or influence over the NOP's decisions concerning the changes to sunset, however, the Board does have the

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<sup>26</sup> 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.greenerchoices.org/pdf/CR2014OrganicFoodLabelsSurvey.pdf>.

<sup>27</sup> Consumer Reports, Greenerchoices Food Safety & Sustainability Center, *Organic Label*, available at <http://www.greenerchoices.org/eco-labels/label.cfm?LabelID=151&searchType=Label&searchValue=organic&refpage=labelSearch&refqstr=label%3Dorganic%26pagenumber%3D5>.

ability to raise concerns and demand change—both verbally and through its actions. The Board also has the ability to hold the NOP to the very standards and procedures of its own creation.

It does nothing for organic consistency and integrity to state in a 2016 sunset proposal that “the... Subcommittee believes that the full Board should have the opportunity to complete the review of each sunset material by voting” and then proceed to explain that the only way to achieve this belief is pre-emptively to vote to remove a material in order deliberate to re-list it. This dishonest process is convoluted and deceptive.

To avoid further confusion, inconsistency, and erosion of organic integrity, we urge all of the subcommittees and NOSB as a whole to demand that the NOP’s Sunset Notice be subjected to notice and comment and that these identified problems, as well as other within the notice be corrected.

We also continue to urge the NOSB in the interim to apply extra caution during sunset materials review. Any material approved for listing on the National List is much more likely to remain on the National List in perpetuity. We believe that the NOP’s decision minimizes all incentives for creating organic, natural alternative ingredients and lowers the standard for what consumers can expect behind the organic label.

Potentially allowing an indefinite listing of non-natural ingredients and requiring a super-majority vote to retire a substance after five years undermines the spirit of the law for how materials head into “sunset” or retirement. It is unfair to producers trying to produce a truly organic product and it is unfair to consumers trying to make meaningful purchasing decisions. Simply put, this lowers the bar for much of the organic market.

## **HANDLING SUBCOMMITTEE**

### **Petitions**

#### ***Whole Algal Flour***

We thank the Handling Subcommittee for its proposal to reject the petition to add “whole algal flour” to the National List. We agree with the Handling Subcommittee that whole algal flour fails to meet OFPA’s essentiality and compatibility criteria.

We urge the NOSB to reject the petition for whole algal flour.

#### **Human Health and Environmental Impacts**

Whole algal flour is a new food ingredient, which was self-determined as “Generally Recognized as Safe” by its manufacturer in April 2013. The FDA accepted this self-determination in June 2013. The FDA does not require or perform independent safety testing. The FDA’s GRAS Notification system, whereby food manufacturers make their own determination regarding the safety of their own food additives, has been widely criticized as inadequate for protecting consumers.

#### **Necessity and Essentiality**

We agree with the Handling Subcommittee that “whole algal flour” is not necessary for the production or handling of organic foods. The petitioner states that “whole algal flour” could be used in organic foods to provide a “healthy alternative” to organic cream, milk, eggs, and/or butter. Since whole algal flour is petitioned as an alternative to organic foods, the organic alternative to whole algal flour is organic food.

We understand that the petitioner plans to market organic foods with whole algal flour to consumers who choose not to or cannot eat foods derived from animals. However, for these consumers, there are plenty of certified organic plant-based foods available.

#### **Compatibility with Organic Farming and Handling**

We also agree with the Handling Subcommittee that whole algal flour is not consistent with organic farming and handling. As defined by the NOSB in 1997, organic agriculture is an “ecological production management system that promotes and enhances biodiversity, biological cycles, and soil biological activity. It is based on minimal use of off-farm inputs and on management practices that restore, maintain, or enhance

ecological harmony. The primary goal of organic agriculture is to optimize the health and productivity of interdependent communities of soil life, plants, animals and people.” The petition for whole algal flour did not disclose the manufacturing process, but other sources (e.g. GRAS notifications filed with the FDA) indicate that whole algal flour is produced from cryo-preserved micro algae in sterile industrial fermenters that never come in contact with the soil or sun and are entirely removed from ecological systems.

We also disagree with Solazyme’s claims that organic milk, cream, butter and eggs are “unhealthy,” and that its algal powder would provide a “healthy” alternative to organic foods.

### **Conclusion**

We agree with the Handling Subcommittee’s proposal to reject the whole algal flour petition, and urge the NOSB to vote “no.”

### ***Ammonium Hydroxide***

We thank the Handling Subcommittee for its proposal to reject the petition to add ammonium hydroxide to the National List as a boiler water additive. We agree with the Handling Subcommittee’s determination that ammonium hydroxide can have potential negative human health and environmental impacts, is not essential because of the availability of alternatives, and is not compatible with organic agricultural and handling.

Results from our 2014 nationally representative consumer survey show that the vast majority of US consumers (91%) think the organic label on packaged and processed foods should mean that no artificial materials are used during processing.

We urge the NOSB to reject the petition for ammonium hydroxide.

### **Human Health and Environmental Impacts**

Ammonium hydroxide is a toxic substance, and is hazardous to human health and the environment.

According to the Material Safety Data Sheet (MSDS) for WET-1133, a boiler water additive made from ammonium hydroxide for use in dairy processing plants, the material is hazardous to human health.

The 2001 TAP review for ammonium hydroxide stated: “exposure to humans and other mammals by ammonium hydroxide is a serious toxicological concern.”

Environmental Protection Agency (EPA) regulations list ammonium hydroxide in several places as a “hazardous substance.” Under 40 CFR 302.4, regulations for the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), ammonium hydroxide is included in the “list of hazardous substances and reportable quantities.” Ammonium hydroxide also appears under 40 CFR 116, which designates hazardous materials under the Federal Water Pollution Control Act (“Clean Water Act”).

### **Necessity and Essentiality**

Handlers processing organic products have managed without the use of ammonium hydroxide for years. Processors in certain areas of the country do not encounter “acid attack” or corrosion in the condensate lines, since the hardness of the water supply is not a problem. Other processors use water softeners, reverse osmosis or management practices that make the use of ammonium hydroxide in organic processing unnecessary and therefore not essential to organic handling.

The petition suggested that adding ammonium hydroxide to the National List will “harmonize” US regulations. However, the Pasteurized Milk Ordinance, FDA regulations for boiler water additives and USDA regulations all currently do not list ammonium hydroxide as an allowed water boiler additive. We also disagree that US regulations should be “uniform,” since consumers expect the organic standards to go above and beyond other US regulations regarding food safety and sustainability.

### **Compatibility with Organic Farming and Handling**

Toxic and hazardous synthetic substances such as ammonium hydroxide are not compatible with organic farming and handling.

### **Conclusion**

We agree with the Handling Subcommittee’s proposal to reject the petition for ammonium hydroxide and urge the NOSB to vote “no.”

### ***PGME***

We thank the Handling Subcommittee for its proposal to reject the petition to add PGME to the National List as a boiler steam additive for use in feed pellet mills. We agree that PGME, which is synthesized from the three toxic materials butanol, propylene oxide and ethylene oxide, could have adverse effects on the environment. It appears that natural alternatives are available, and the material is therefore not essential. We also agree that this substance, made from toxic petroleum-based products, is not compatible with organic farming and handling.

We urge the NOSB to reject the petition for PGME.

### ***Triethyl Citrate***

We thank the Handling Subcommittee for its proposal to reject the petition to add triethyl citrate to the National List. It appears that alternatives exist and triethyl citrate fails to meet the “essentiality” requirement for inclusion on the National List.

We urge the NOSB to reject the petition for triethyl citrate.

### ***Ancillary Substances in Microorganisms***

We are pleased that the Handling Subcommittee is requesting information about ancillary substances during sunset review, and listing these substances during sunset review. This is a step in the right direction as it improves transparency regarding all ingredients used to produce organic foods.

We continue to believe 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.

We reiterate our comment prior to the Spring 2014 NOSB meeting:

#### ***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.

We appreciate the Handling Subcommittee's efforts to gather information about ancillary substances for materials up for sunset review, and its listing of these substances. However, we do not agree that simply stating that "there is no literature to suggest that microbial preparations with ancillary substances have negative effects on human health" constitutes adequate review.

**The policy should be strengthened to preserve organic integrity.**

We continue to urge the NOSB to revisit the recommendation on ancillary substances. If an organic handler believes that a material on the National List cannot be sourced without a particular synthetic and unapproved "other ingredient," then that ingredient should be petitioned to be added to the National List with an annotation restricting its use to the materials for which it is needed.

This approach:

- Respects OFPA and the requirement for *all ingredients* to be organic or on the National List.
- Is in line with OFPA's specification that substances on the National List shall be listed "by specific use or application." The NOSB can recommend that a synthetic ingredient be approved only for the particular ingredient for which its use is petitioned.
- Addresses the difficulties raised by the fact that other ingredients may vary from manufacturer to manufacturer. If a particular manufacturer, or an organic handler who uses the ingredient, knows that a particular "other ingredient" is used and believes its use is necessary, that particular ingredient can be petitioned by the manufacturer or organic handler.
- Increases transparency by requiring handlers and manufacturers to disclose the unapproved "other ingredients" that are used.
- Preserves consumer trust in the organic label and the process. The public has a right to know *all* ingredients used in the production of organic foods.

We urge the Board to revisit the recommendation and strengthen it, clarifying that only single substances may appear on the National List and that all ingredients added to organic foods should be either organic or on the National List.

Any ingredients considered essential as components of materials on the National List should be petitioned for that particular purpose, with an annotation specifying the approved use.

## **Sunset 2016 Reviews Meeting 2**

### ***Volatile amines***

#### Cyclohexylamine, Diethylaminoethanol and Octadecylamine

We thank the Handling Subcommittee for its proposals to remove three volatile amines from the National List. We agree with the Handling Subcommittee's determination that these substances can pose serious risks to human health and the environment, are not essential, and are not compatible with organic handling.

Our survey results show that the vast majority of consumers (76%) do not know that artificial materials are used during the processing of organic foods. And 91% of US consumers think the organic label on packaged and processed foods should mean that no artificial materials are used during processing.

These consumer beliefs and expectations are consistent with OFPA, which addresses the use of toxic substances in package sterilization: "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, use any bag or container that had previously been in contact with any substance in such a manner as to compromise the organic quality of such product."<sup>28</sup>

The Handling Subcommittee's proposal is also consistent with the initial TAP review, in which the three reviewers wrote that these chemicals are incompatible with organic production, and recommended that they not be allowed.

The reviewers wrote that organic food production requires changing systems. Just as a farm makes changes to its overall system to eliminate its dependence on toxic chemicals for pest control and soil fertility, so processing facilities must make changes to eliminate the need for toxic chemicals. From the TAP review: "The inconvenience of having to retool or readjust systems should not be the determining factor in whether or not such materials are added to the National List." However, it appears these three substances were approved based on the cost to handlers of using natural alternatives.

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<sup>28</sup> 7 U.S.C. 6510 (a)(6)

We appreciate the Handling Subcommittee’s determination that these substances should be removed from the National List, and urge the NOSB to vote “yes” to remove them from the National List.

### ***Phosphate food additives***

#### sodium acid pyrophosphate and tetrasodium pyrophosphate

We urge the NOSB to consider the latest scientific research on negative human health impacts from the consumption of phosphate food additives. This research applies to two materials on 205.605(b) that are up for 2016 sunset review (and three materials up for 2017 sunset review - see comments below).

### **Human Health Impacts**

Phosphorus is an essential nutrient. Deficiency is rare, and often only observed in cases of near-total starvation or in rare inherited disorders. Concerns with phosphorus in the diet arise not from low intake and deficiencies, but from high intake which is associated with negative impacts on bone health, kidney health and heart health.<sup>29</sup>

Phosphorus homeostasis appears to be regulated by a complex endocrine feedback system,<sup>30</sup> and recent science has identified specific hormones that are involved in phosphorus homeostasis. These findings have shed light on the different mechanisms by which high phosphorus intake can lead to negative impacts health, and are especially relevant to the discussion of phosphate food additives, for several reasons.

Phosphate food additives are more readily absorbed during digestion than naturally occurring phosphorus in foods, and lead to a higher phosphorus load.<sup>31 32</sup> Due to the popularity of phosphate food additives in the processed foods industry, levels of

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<sup>29</sup> Guitierrez OM. 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.

<sup>30</sup> Ritz E, Hahn K, Ketteler M, Kuhlmann MK, Mann J. 2012. Phosphate additives in food—a health risk. *Dtsch Arztebl Int* 109(4): 49–55; doi: 10.3238/arztebl.2012.0049 . Page 50.

<sup>31</sup> 40%-60% absorption for naturally occurring phosphorus vs. 70-100% absorption for phosphates

<sup>32</sup> Ritz E, Hahn K, Ketteler M, Kuhlmann MK, Mann J. 2012. Phosphate additives in food—a health risk. *Dtsch Arztebl Int* 109(4): 49–55; doi: 10.3238/arztebl.2012.0049. Page 53.

Anderson JJ. 2013. Potential health concerns of dietary phosphorus: cancer, obesity, and hypertension *Ann. N.Y. Acad. Sci.* 1301 (2013) 1–8. page 1.

Chang AR et al. 2014. High dietary phosphorus intake is associated with all-cause mortality: results from NHANES III. *Am J Clin Nutr* 2014;99:320–7.

phosphorus intake and phosphorus load are believed to have increased dramatically in recent years.

One of the hormones identified in regulating serum phosphorus concentrations is Fibroblast Growth Factor 23 (FGF-23).<sup>33</sup> The first study published on FGF-23 we located in Pubmed was published in 2001,<sup>34</sup> which makes this “new” information that has not been considered in NOSB evaluations of any of the phosphate food additives currently approved for use in organics.

In a review presented at the symposium “Dietary Phosphorus Excess: A Risk Factor in Chronic Bone, Kidney, and Cardiovascular Disease” held 24 April 2013 at the ASN Scientific Sessions and Annual Meeting at Experimental Biology 2013 in Boston, MA, the authors wrote: “Although phosphorus is an essential nutrient, its excess could be linked to tissue damage by a variety of mechanisms, including the secretion and action of fibroblast growth factor-23 (FGF-23) and parathyroid hormone (PTH). Disordered regulation of these hormones by high dietary phosphorus may be key factors contributing to renal failure, atherosclerosis, and osteoporosis. Many epidemiological studies show that mild elevations of serum phosphorus within the normal range are associated with CVD risk in healthy populations in the absence of apparent kidney disease.”<sup>35</sup>

### **Necessity and Essentiality**

***Sodium acid pyrophosphate:*** Other raising agents, which do not contain phosphates, are available. While phosphate-containing raising agents may be useful to handlers, due to increased control during the baking process, we do not believe that they are essential. There appear to be natural alternatives for sodium acid pyrophosphate, which is used as an acid to react with sodium bicarbonate to produce a controlled release of carbon dioxide that leavens the baked product. Baking powder with natural and certified organic acids, such as organic grape juice concentrate extracts, is currently available.

It is also worth noting that the standards for the Demeter Biodynamic label specifically prohibit the use of phosphate-containing raising agents.

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<sup>33</sup> Ritz E, Hahn K, Ketteler M, Kuhlmann MK, Mann J. 2012. Phosphate additives in food—a health risk. *Dtsch Arztebl Int* 109(4): 49–55; doi: 10.3238/arztebl.2012.0049. Page 50.

<sup>34</sup> Guitierrez OM. 2013. Fibroblast growth factor 23, Klotho and disordered mineral metabolism in chronic kidney disease: unraveling the intricate tapestry of events and implications for therapy. *J Ren Nutr.* 23(3): 250–254. doi:10.1053/j.jrn.2013.01.024.

<sup>35</sup> Uribarri J and Calvo MS. 2013. Dietary Phosphorus Excess: A Risk Factor in Chronic Bone, Kidney, and Cardiovascular Disease? *Adv. Nutr.* 4: 542–544, 2013; doi:10.3945/an.113.004234.

***Tetrasodium pyrophosphate***: We agree with the Handling Subcommittee that tetrasodium pyrophosphate is not essential to organic handling, as certified organic vegan foods can be made without it.

### **Compatibility with Organic Farming and Handling**

The majority of US consumers do not believe that the use of artificial ingredients is consistent with organic principles. Our April 2014 survey found that 74% of U.S. consumers currently think the organic label means the food is free from artificial ingredients, and 89% think that organic foods should be free from artificial ingredients.

The use of Sodium Acid Pyrophosphate in products labeled “natural” has been the subject of multiple class-action lawsuits. Furthermore, in September 2014, the FDA sent a warning letter to a Massachusetts bakery, which contained the following: “your liveGfree Blueberry Pancakes are misbranded ... because it bears the claim “ALL NATURAL” but contains sodium acid pyrophosphate, which is a synthetic substance.”

### **Conclusion**

The NOSB should consider recent scientific findings on the potential impacts on human health from the consumption of phosphate food additives. No single phosphate food additive, in isolation, will be consumed in quantities that put a consumer at risk. Rather, it is the widespread use of phosphate food additives in processed foods that raises concerns. The NOSB should consider these impacts when evaluating any phosphate food additive, considering that any phosphate food additive will be a contributing factor for consumers who eat processed foods.

### **Sunset 2017**

For Sunset 2017, there are 23 listings for 205.605(a), 31 listings for 205.605(b), and 24 listings for 205.606. We have not included written comment on all materials for Sunset 2017, but this does not mean that we support the use of substances for which we have not provided written comments. We plan to continue to research these materials, and if human health or environmental concerns come to light, we plan to present these findings and would expect the NOSB to consider them prior to the vote. We do not believe that research should be considered “untimely” if it is presented after the comment period for “meeting 1” has ended. We believe it is the NOSB’s responsibility to ensure that OFPA criteria for inclusion on the National List are met, regardless of when the information is presented to the NOSB.

### ***Phosphate food additives***

Phosphate food additives that are up for 2017 Sunset review, and the date of their most recent technical evaluation, include:

- sodium phosphates (2001 TAP)
- potassium phosphate (1995 TAP)
- calcium phosphate (1995 TAP)

As noted above in our discussion on phosphate food additives for Sunset 2016 materials, phosphate food additives have been associated with negative impacts on bone health, kidney health and heart health. Recent research — all published since the last TAP review was performed in 2001 — shows that phosphorus homeostasis is tightly regulated by the endocrine system. High concentrations of one of the hormones that has been identified as regulating phosphorus homeostasis has been linked with heart failure, cardiovascular events, chronic kidney disease progression, and mortality.<sup>36</sup>

Medical researchers who study the impacts of phosphates on human health consistently voice their concerns with the widespread use of these food additives in processed foods. Calvo and Uribarri (2013) write:

The increasing cumulative use of phosphorus-containing additives is quite dramatic. Any average person’s refrigerator or pantry will show that the majority of processed food products consumed for breakfast, lunch, dinner, or snacks contain phosphorus as one or more added ingredients. Although the actual amount of phosphorus in each item may be low, the total phosphorus consumed over a 24-h period may become quite considerable.

### **Essentiality**

Phosphate food additives should not be used if they are merely “useful” to processors, especially given their impact on human health. If the additive is not essential, it should not be used to protect organic consumers from high phosphorus load. We identified several organic processed foods that contain phosphate food additives, and identical products by other manufacturers that do not contain these additives:

	<b>Contains phosphate food additives</b>	<b>No phosphate food additives</b>
<b>Mac n Cheese</b>	Horizon, Annie’s	Kraft, Back to Nature, Amy’s
<b>Cottage Cheese</b>	Horizon	Organic Valley

<sup>36</sup> [Chang et al 2014, page 320]

	Contains phosphate food additives	No phosphate food additives
Yogurt in tubes	Horizon	Stonyfield
Egg whites	Horizon	Organic Valley

These additives do not appear to be essential, and fail the criteria in OFPA for inclusion on the National List.

### ***Nutrient Vitamins and Minerals***

We are concerned with the widespread and seemingly indiscriminate addition of synthetic and non-organic “nutrients” to organic foods. For the 2017 Sunset review of “Nutrient Vitamins and Minerals” on 205.605(b), we urge the NOSB to remove “nutrient vitamins and minerals” from the National List.

### **Background**

Currently, the annotation accompanying the “nutrient vitamins and minerals” listing states: “in accordance with FDA 21 CFR 104.20, Nutritional Quality Guidelines for Foods.”

FDA 21 CFR 104.20(d)(3) lists 21 vitamins and minerals that “may be added to food.” However, the National Organic Program has interpreted the current annotation in such a way that it allows any synthetic “nutrient” in organic foods, because 21 CFR 104.20(f) states: “Nutrient(s) may be added to foods as permitted or required by applicable regulations established elsewhere in this chapter.”

However, elsewhere in 21 CFR 104.20, the FDA states: “The Food and Drug Administration does not encourage indiscriminate addition of nutrients to foods.” Unfortunately, the NOP in the past chose to refer to 21 CFR 104.20(f) instead as the basis for allowing nutrient additives that have not been petitioned and approved for use in organics.

After consultation with the FDA, the NOP issued a memo on April 26, 2010, prior to the 2010 sunset review of “nutrient vitamins and minerals.” The NOP acknowledged that its “previous interpretation of 21 CFR 104.20 was incorrect.” The FDA also clarified that “21 CFR 104.20 does not apply to the use of substances such as DHA and ARA oil, taurine, or sterols that have been added to products such as infant formula, milk, pet food, or energy bars as nutrients.”<sup>37</sup>

<sup>37</sup> <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5084068&acct=n>

The NOP asked the NOSB to “reevaluate their recommendation for nutrient vitamins and minerals during the 2012 sunset process, and provide specific recommendations regarding the scope of permitted vitamins, minerals and nutrients in organic foods.”<sup>38</sup>

The NOSB recommended to relist “nutrient vitamins and minerals” with the existing annotation.<sup>39</sup> However, in January 2012, the NOP released a proposed rule to change the annotation of “nutrient vitamins and minerals.” According to the NOP, this was to “correct an inaccurate cross reference to FDA regulations in the listing for vitamins and minerals on the National List.”<sup>40</sup>

The NOP proposed the following annotation: “For food – vitamins and minerals identified as essential [by the FDA] in 21 CFR 101.9. For infant formula – vitamins and minerals as required by [FDA] 21 CFR 107.100 or sec. 107.10.” The NOP wrote that it chose 21 CFR 101.9 based on “recent consultation with the FDA,” which “clarified that 21 CFR 101.9 does identify essential vitamins and minerals.”<sup>41</sup>

Despite widespread support for changing the annotation from all segments of the organic community, in September 2012 the NOP released an interim rule that “renews, without change, the exemption (use) for nutrient vitamins and minerals on the National List.”<sup>42</sup>

Today, the original listing and annotation remain, and even synthetic nutrients that have been petitioned and *rejected* by the NOSB continue to appear in organic foods. Specifically, the NOSB voted in the Fall 2012 to reject petitions for synthetic taurine,<sup>43</sup> l-methionine (except for soy-based infant formula),<sup>44</sup> lycopene,<sup>45</sup> lutein,<sup>46</sup> l-carnitine<sup>47</sup> and

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<sup>38</sup> <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5084068&acct=n>

<sup>39</sup> <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5091724>

<sup>40</sup> <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5096390>

<sup>41</sup> <http://www.regulations.gov/#!documentDetail;D=AMS-NOP-10-0083-0001>

<sup>42</sup> <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5100713>

<sup>43</sup> <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5101291>

<sup>44</sup> <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5101289>

<sup>45</sup> <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5101287>

<sup>46</sup> <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5101286>

<sup>47</sup> <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5101288>

nucleotides.<sup>48</sup> Synthetic or non-organic versions of these nutrients continue to appear in organic infant formula and organic baby foods.

### **Essentiality**

Only synthetic nutrients that are required by law should be considered “necessary to the production or handling of the organic product because of the unavailability of wholly natural substitute products.” Adding these synthetic nutrients directly to organic foods should not be considered a “necessary” step to producing organic foods.

### **Compatibility & Consistency with organic farming and handling**

Synthetic nutrients for soil are prohibited in organic standards — a basic principle of organic farming. With few exceptions (e.g., methionine), synthetic nutrients in livestock feed are prohibited in organic standards. The allowance of synthetic nutrients in organic foods creates inconsistency in the organic standards. More inconsistency arises when some certifiers follow the FDA's interpretation of the annotation (only nutrients listed under 104.20(d)(3) should be added to foods) while others allow any synthetics nutrients to be added to organic foods, including those that do not appear on this list and are not classified by science or the FDA as “vitamins” or “minerals” (e.g., synthetic amino acids).

The vast majority of US consumers agree that artificial ingredients are not compatible with organic handling. In our 2014 nationwide surveys, we found that:

- 71% of US consumers believe as few artificial ingredients as possible should be approved for use in organic foods
- 74% of US consumers think that the organic label means no artificial ingredients are used
- 89% of US consumers think that the organic label *should* mean no artificial ingredients are used.

### **205.600 Criteria**

The regulations state:

§205.600 Evaluation criteria for allowed and prohibited substances, methods, and ingredients.

The following criteria will be utilized in the evaluation of substances or ingredients for the organic production and handling sections of the National List:

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<sup>48</sup> <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5101290>

(b) In addition to the criteria set forth in the Act, any synthetic substance used as a processing aid or adjuvant will be evaluated against the following criteria:

(4) **The substance's primary use is not as a preservative or to recreate or improve flavors, colors, textures, or nutritive value lost during processing, except where the replacement of nutrients is required by law;** (emphasis added)

The primary purpose of any synthetic nutrient will be to replace or improve nutritive value lost during processing, or to add nutrients that were never meant to be in the food in the first place. Only a handful of synthetic nutrients are required by law, and these should be individually petitioned and added to the National List.

## **Conclusion**

The current listing and annotation for “nutrient vitamins and minerals” on the National List has led to the indiscriminate addition of synthetic nutrients to organic foods. The addition of synthetic nutrients to organic foods should be restricted to those that are required by law, and whose absence would prevent the sale of an organic version of the product. Otherwise, no synthetic nutrient is “necessary.”

We urge the NOSB to remove “nutrient vitamins and minerals” from the National List. The handful of nutrients that are required by law and are not yet on the National List should be petitioned individually, with an annotation specifying that it should only be added to foods that are required by law to contain that particular nutrient in a synthetic version.

## ***Flavors***

The primary use of flavors is to recreate or improve flavors. 205.600(b)(4) states that substances should not be added to the National List if their primary use is to recreate or improve flavors.

Demeter Biodynamic has the following requirement for the use of flavors in processed foods:

“Flavorings should be from good quality DEMETER CERTIFIED BIODYNAMIC or certified organic sources. Pretending taste by adding flavors is not allowed. Pure extracts as well as herbs and spices may be used to round off the products.”

We also found “organic natural flavors” which list as their ingredients organic oils or other organic carriers and “natural flavor.” It appears that these materials are labeled as

“organic” even though the natural flavor is not organic, only the carrier is. We urge the NOSB to find out what those “natural flavors” are, how they are made, and what the starting materials are.

### ***Xanthan gum***

The primary use of xanthan gum is to recreate or improve texture. 205.600(b)(4) states that substances should not be added to the National List if their primary use is to recreate or improve textures.

The last technical report for xanthan gum is a TAP review done twenty years ago, in 1995.

In 2011, the Centers for Disease Control and Prevention and the Food and Drug Administration warned parents and caregivers not to feed a xanthan gum thickener to premature infants, because it “may cause necrotizing enterocolitis (NEC), a life-threatening condition characterized by inflammation and death of intestinal tissue.”<sup>49</sup> An article in the *Journal of Pediatrics* identified 22 cases of necrotizing enterocolitis linked with ingestion of xanthan gum in 2011.<sup>50</sup> The *New York Times* reported seven deaths of infants and 14 cases of infants needing surgery after receiving xanthan gum.<sup>51</sup>

Given these reports, and potential concerns about xanthan gum’s human health impacts, we believe that xanthan gum should have an updated technical review before the Sunset vote at the Fall 2015 meeting.

### **Sunset 2017 - 205.606**

#### ***Inulin-oligofructose enriched and Fructooligosaccharides***

We urge the NOSB to remove “inulin-oligofructose enriched” and “fructooligosaccharides” from the National List in 2017. We believe these materials fail to meet the criteria in OFPA for inclusion on the National List because they are not necessary to the production or handling of organic products. We also believe these substances do not meet the definition of “agricultural products.”

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<sup>49</sup> <http://www.fda.gov/NewsEvents/newsroom/PressAnnouncements/ucm256253.htm>

<sup>50</sup> Beal J et al. 2012. Late onset necrotizing enterocolitis in infants following use of a xanthan gum-containing thickening agent. *Journal of Pediatrics* 161(2):354-6. doi: 10.1016/j.jpeds.2012.03.054.

<sup>51</sup> [http://well.blogs.nytimes.com/2013/02/04/warning-too-late-for-some-babies/?\\_r=0](http://well.blogs.nytimes.com/2013/02/04/warning-too-late-for-some-babies/?_r=0)

## **Necessity and Essentiality**

As discussed above, materials on 205.606 must meet all criteria in OFPA, including the requirement that it be “necessary.” Inulin-oligofructose enriched (IOE) and fructooligosaccharides (FOS) do not meet this requirement.

IOE and FOS are highly processed isolates of sugars that are derived from foods such as chicory, bananas and garlic. They are added to foods to allow the manufacturer to make certain marketing claims related to the perceived health benefits of highly isolated fibers and sugars. In public comment during the Spring 2007 NOSB meeting, organic food manufacturers argued in favor of adding these ingredients to the National List, and based arguments of their “necessity” on the role of inulin in preventing whey separation in yogurt as well as the marketing benefits of making health claims.<sup>52</sup>

IOE and FOS present a case study for how the OFPA criteria have been ignored for 606 materials. Transcripts from the Spring 2007 NOSB meeting suggest that industry representatives and some NOSB members argued that materials petitioned for 205.606 did not need to meet the OFPA criteria for being “necessary to the production and handling of organic products.” In fact, it appears that a major driving factor behind the arguments for classifying IOE and FOS as “agricultural” was the shared perception that questions of necessity and compatibility would not apply.<sup>53</sup>

There is a difference between ingredients that are “necessary to the production and handling of the agricultural product because of the unavailability of wholly natural substitute products” and ingredients that are “useful.”

Sometimes the line between what is necessary and what is useful is not clear, but the line is clear in the case of IOE and FOS. IOE and FOS are not necessary; they are useful as marketing tools. It is entirely possible to make yogurt, frozen yogurt, milk and bread without either FOS or IOE.

We urge the NOP and NOSB to distinguish between “necessary” ingredients and “useful” ingredients. Merriam-Webster defines “necessary” as “so important that you do it or have it: absolutely needed.” Oxford dictionary defines “necessary” as “required to be done, achieved, or present; needed; essential.” These ingredients are not needed, required or essential in any foods.

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<sup>52</sup> Spring 2007 NOSB meeting transcript, Tuesday, page 71

<sup>53</sup> (Wed page 66 lines 9-14)

As a source of sugars and fibers, and as with any other isolated component of food that is added for purported nutritional health benefits, the “wholly natural substitute product” would be food.

### **Classification of Inulin**

In March 2007, prior to the Spring 2007 NOSB meeting, the Handling Committee proposed that inulin-oligofructose enriched (IOE) should be classified as a 205.605 material. During the NOSB meeting, the petitioner and several others in the industry argued in public comment that the material should be listed as an “agricultural” on 205.606 instead, using the following arguments:

“Oligofructose enriched inulin belongs on 606 because it’s derived from plants, it will be available organically at some point, and development of the supply should be encouraged.”

The 2015 Technical Report (TR) for inulin notes that while it is indeed derived from a plant, it is highly processed, using synthetic processing aids:

“The inulin extract is purified using lime (calcium hydroxide) and carbonation, leaving behind various precipitates, proteins, peptides, and colloids that may be used as a soil amendment by farmers (De Leenheer, 1996). The inulin extract is filtered first using ion exchange using inputs of ammonia and sulfuric acid; the liquid is then filtered again using activated carbon (De Leenheer, 1996). Byproducts of this process are ammonium sulfate and potassium sulfate, which are precipitated out of solution and sold as conventional (i.e., not for use in organic agriculture) fertilizer (De Leenheer, 1996).”<sup>54</sup>

The TR then describes the enzymes used for enzymatic hydrolysis that leads to the chemical change, and states:

“The hydrolysis is a chemical change, and although the change occurs using an enzyme from a fungus (the inulinase in *Aspergillus niger*), this is not a process that occurs in nature.”<sup>55</sup>

We do not believe that inulin-oligofructose enriched meets the definition of “agricultural” in the organic regulations, 7 CFR 205:

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<sup>54</sup> (TR line 287-292)

<sup>55</sup> TR line 300-302

*“Nonagricultural substance. A substance that is not a product of agriculture, such as a mineral or a bacterial culture, that is used as an ingredient in an agricultural product. For the purposes of this part, a nonagricultural ingredient also includes any substance, such as gums, citric acid, or pectin, that is extracted from, isolated from, or a fraction of an agricultural product **so that the identity of the agricultural product is unrecognizable** in the extract, isolate, or fraction.”* (emphasis added)

Moreover, it appears that many companies, including those that argued for the inclusion of inulin on 205.606, now list “organic inulin” as an ingredient.

### **Classification of Fructooligosaccharides**

When FOS are listed as an ingredient, it is not identified by the agricultural starting material. Rather, FOS is identified by its trade names, which include “Neosugar” and “NutraFlora.”

Fructooligosaccharides (FOS) are a highly processed isolate of an agricultural product and should not be listed as an agricultural on 205.606. As with inulin discussed above, the definition in 7 CFR 205 does not apply. The 2015 FOS Technical Report (TR) notes:

“FOS are not naturally available from unprocessed foods, but must be released from inulin through partial hydrolysis or chemical breakdown by reaction with water.”

It appears that FOS is derived from further processing of inulin, already a highly processed product (see discussion above). It is also unclear which agricultural product is used as the starting material for FOS production, although the TR states that “chicory is the most commonly used vegetable source for the industrial production of inulin.”<sup>56</sup>

### **Conclusion**

We urge the NOSB to remove inulin-oligofructose enriched and fructooligosaccharides from 205.606 of the National List because these materials are not necessary. They also should be listed on 205.606 because they do not meet the definition of “agricultural substance.”

### ***Fish oil***

Fish oil is added for marketing purposes, to allow manufacturers to make health claims in an effort to entice consumers to purchase their product over a less processed one.

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<sup>56</sup> TR line 66-67

Products such as yogurt and bread can be made without fish oil; fish oil is therefore not necessary and fails to meet the OFPA criteria.

The OFPA also requires environmental impacts to be considered. We also have concerns about possible heavy metal contamination of some fish oil, and the environmental and sustainability impacts from the fisheries that harvest the fish.

A recent New York Times article again questions the purported health benefits of fish oil supplements.<sup>57</sup>

## ***Colors***

### **Human Health and Environmental Impacts**

NOSB must consider the human health and environmental impact of producing colors derived from non-organic crops, which should include a review of the pesticides used to grow them. For example, there are three colors on the National List that are derived from non-organic carrots:

- “beta-carotene extract color — derived from carrots or algae”
- “carrot juice color”
- “black/purple carrot juice color”

In March 2015, Consumer Reports released a report, “From Crop to Table: Pesticide Use in Produce,” in which we analyzed various sources of data to assess risk from pesticide residues on fruits and vegetables. For carrots, we advised consumers to always look for organic. Specifically, USDA Pesticide Data Program (PDP) tests for 2013 show detectable residues on more than 10% of carrot samples of the pesticides linuron, trifluralin, iprodione, pyraclostrobin, boscalid, metalaxyl and azoxystrobin. In 2007, PDP testing found nearly 80% of carrots contained residues of linuron, 60% contain residues of trifluralin, and 43% contained residues of pyraclostrobin. This raises concerns with the human health and environmental impacts of conventional carrots.

### **Consistency and Compatibility with Organic Farming and Handling**

The use of colors from conventional crops that are commonly found as organic, such as carrots and blueberries, also creates inconsistency in the marketplace when consumers find conventional crops used in organic foods. If fresh and frozen organic carrots, blueberries, beets and other crops are readily available in the marketplace, consumers

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<sup>57</sup> O’Conner A. March 30, 2015. Fish oil claims not supported by research. New York Times. <http://mobile.nytimes.com/blogs/well/2015/03/30/fish-oil-claims-not-supported-by-research/?referrer=>

would expect colors from these organic crops to be used in organic processed foods as well.

The practices used to grow the conventional crops for color additives are not consistent with organic farming and handling. Many certified organic products contain certified organic colors. At this point, there should be enough organic carrots, organic beets, organic blueberries and organic versions of all the crops used for colors on 205.606 to meet market demand. Removing these materials from the National List will create the demand and incentive for all organic foods on the marketplace to contain organic colors.

## **CROPS SUBCOMMITTEE**

### **Petitioned Substances (Exhaust Gas, Calcium Sulfate, and 3-decene-2-one)**

We support the Crops Subcommittee in all of its recommendations concerning the petitioned substances for inclusion on the National List: Exhaust Gas, Calcium Sulfate, and 3-decene-2-one. In all three instances, the committee reviewed each material according to the National List criteria and found that one or more of the criteria had not been met—leading to a proposal that the material not be listed.

While it is a perplexing matter as to why some of these materials, such as exhaust gas, were petitioned for inclusion in the first place and could ever be considered to meet any of the National List criteria, Consumer Reports appreciates the efforts of the Crops Subcommittee in giving each petition its consideration and thorough review, according to the organic standards consumers expect.

### **Discussion Document: Contamination Issues in Farm Inputs**

The Crops Subcommittee's Contaminated Input Plan offers an encouraging step towards addressing an important issue in organic production and assisting organic farmers to better meet the requirement of avoiding contamination with substances prohibited in organic production.<sup>58</sup> It is incongruent that organic farming standards, which explicitly prohibit synthetics, pesticides, and toxins, allow manures and composts with these substances present. We support the Crops Subcommittee and NOSB as a whole in making every effort to move forward with its Contaminated Input Plan.

### **Sunset**

We refer the NOSB to our general policy comments concerning sunset review and the changes imposed by the NOP, which we believe undermine the organic label and consumers expectations concerning exceptions to organic standards. Concerning the Crops Subcommittee proposals for individual sunset review materials for 2016, we also remind the subcommittee of our general policy comments regarding application of National List criteria at every phase of a substances review, including sunset, and presenting this mandatory analysis in a clear, documented and transparent manner. The public and consumers should be able to ascertain in a straight-forward way whether the

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<sup>58</sup> 7 C.F.R. § 205.203.

material continues to meet the mandatory National List criteria and this was not achieved in the Crops Subcommittee 2016 sunset material proposals.

We also refer the NOSB to our general comments concerning application of the NOP Sunset Rule and its responsibility to communicate its disapproval of the policy changes without creating further confusion and degradation of the sunset review process.

Beyond these general comments, the following outlines our comments for certain sunset material considerations.

## **Sunset 2016 Reviews Meeting 2**

### ***Ferric Phosphate***

We support the members of the subcommittee who voted to remove ferric phosphate due to its ineffectiveness as a sole ingredient and dependency on EDTA, an inert ingredient, to achieve effectiveness.

Understanding that active ingredients must be listed separately, the NOSB cannot evaluate materials in a vacuum. Whether an inert or not, EDTA should not be in use in organic (an issue we will address further under our discussion of inerts) and should be held to the same National List criteria as all substances on the National List. Ferric phosphate is not essential and thus does not meet the National List criteria and should not be renewed.

### ***Hydrogen Chloride***

Consumer Reports believes that Hydrogen Chloride (HCl) does not meet the National List criteria concerning harm to health and the environment and consistency with organic production and that its essentiality continues to be driven by the failure to create demand for natural alternatives and should not be relisted for another five years.

As noted by the Crops Subcommittee, commenters from the first round of 2016 sunset review and the recently completed TR suggest that while several mechanical/natural alternatives exist and are under development, their application is not commercially available. However, several commenters also mentioned the extreme corrosive nature of HCl and the need to develop an alternative delinting method as soon as possible.”

Thus while we recognize that hydrogen chloride is considered essential to obtaining delinted cottonseed, that delinted cotton appears to be somewhat necessary to the production of large-scale organic cotton planting, and the “commercial” availability of wholly natural alternatives is limited, there are in fact alternatives. The Crops Subcommittee’s emphasis on developing these alternatives does not go far enough given

the reduced effectiveness of the sunset review in putting pressure on the organic industry to develop organic alternatives.

Should annotations be allowed at sunset, we believe this would be an effective way to address our concerns while meeting National List criteria by imposing a shorter expiration date. However, since this is not an option we believe that HCl should not be relisted, a compliance date should be set so the industry can immediately begin to build demand for natural alternatives to HCl.

## **Sunset 2017 Sunset Summaries Meeting 1**

### ***7 CFR §205.601 - Chlorine Materials: Calcium hypochlorite, Chlorine dioxide, Sodium hypochlorite***

Consumer Reports recognizes that chlorine materials pose a difficult challenge in organic production context. On the one hand, chlorine is a readily available and effective disinfectant, often viewed as important in meeting food safety standards through all categories of its use (crops, handling, and livestock). However, the production, use, and disposal of chlorine have many documented negative human and environmental health effects, and its use overall is not consistent with organic production standards. While alternative sanitizers and disinfectants—both natural and synthetic on the National List—exist, there remain issues with the supply and demand for wholly natural substitutes.

As we have noted from the outset of these comments, adherence to the standards of organic and National List criteria must be at the forefront of every National List determination. In its past decisions on chlorine, the NOSB took great caution to include the material on National List with a limiting annotation under each of its categories. For use on crops, the use restriction read:

For pre-harvest use, residual chlorine levels in the water in direct crop contact or as water from cleaning irrigation systems applied to soil must not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act, except that chlorine products may be used in edible sprout production according to EPA label directions.<sup>59</sup>

The intention behind this annotation and others was to limit chlorine's health and environmental impacts to those established for drinking water, thus better aligning chlorine with the National List criteria.

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<sup>59</sup> 7 C.F.R. § 205.601.

As a member of NOC, Consumer Reports is united in NOC's concern about the NOP clarification on the use of chlorine,<sup>60</sup> which allows for a higher concentration than allowed in the Safe Water Drinking Act, to be used in wash tanks, especially for organic food products that could absorb this higher concentration of chlorine into the food. Neither NOC nor Consumer Reports believe this clarification was the intent of the NOSB and is not consistent with OFPA National List criteria. Poultry, eggs, leafy vegetables, root crops and more could absorb highly chlorinated water and the final effluent after the wash tank could still only contain the required 4 PPM.

Consumer Reports supports the recommended annotation proposed by NOC to address this concern, but also recognizes the need to preserve disinfecting and sanitization needs for individual application. The annotation as presented by NOC reads:

Chlorine materials, only present as residual chlorine levels in water delivered by municipal or other public water systems, which shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.

- (i) Calcium hypochlorite.
- (ii) Chlorine dioxide.
- (iii) Sodium hypochlorite.

We recommend that this annotation be a foundational standard, but that individual applications and uses be included in the listing where necessary for sanitary purposes. In setting those individual application annotations, we support NOC's recommendations that the following additional factors considered:

The use of chlorine on food contact surfaces should be handled separately from the use of dissolved chlorine in tank situations, especially on foods that can absorb some of the wash water.

To be consistent, the use of other approved disinfectant products in wash tank water systems should also be reviewed as to the possibility of absorption, at what concentration, and any negative health effects. This would include peracetic acid.

Based partly on the efforts of EPA's Design for the Environment results, prioritize research on a variety of cleaning and disinfection materials for use in organic food processing, especially those that would be readily available, at a reasonable price and effective in a variety of situations. Moreover, EPA's DFE does not allow chlorine

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<sup>60</sup> U.S. Dept. of Agriculture, Guidance: The Use of Chlorine Materials in Organic Production and Handling, NOP 5026, July 22, 2011, available at <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5090760>

products to be used for disinfection further documenting its incongruence with organic standards.

We recognize that because the NOSB has been banned from annotating National List materials during the sunset review process, these recommendations may pose a logistical issue. Accordingly, we propose that the NOSB make every effort to bring forward its own parallel proposal, addressing these concerns.<sup>61</sup>

Just because chlorine is on the National List and the NOP has offered misguided interpretations of the NOSB's efforts to ensure that National List materials align with OFPA criteria does not mean that the NOSB should surrender its well-founded intentions. For chlorine's use to continue to meet the necessary OFPA National List criteria, we strongly urge the NOSB to consider whatever means are possible to make the suggested annotations and clarifications.

### ***7 CFR §205.601 - Copper (Fixed and Sulfate)***

We urge the NOSB to consider the human health and environmental impacts of copper.

#### **Human Health and Environmental Impacts**

Copper is highly toxic to aquatic invertebrates and fish. According to the EPA: "The mode of toxicity for aquatic organisms is different than for terrestrial animals in that copper rapidly binds and causes damage to the gill membranes, and interferes with osmoregulatory processes."<sup>62</sup>

When evaluating the potential for risk to aquatic animals from the use of copper in agricultural uses, the EPA wrote in its 2006 RED:

The screening-level risk assessment indicates that there are risks greater than the LOC to freshwater invertebrates from terrestrial uses of copper at some portion of the 811 sites modeled, regardless of the application rate. At the maximum label application rate considered in the risk assessment, 31.8 pounds of metallic copper

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<sup>61</sup> See, e.g., National Organic Standards Board, Formal Recommendation by the National Organic Standards Board (NOSB) to the National Organic Program (NOP), *Chlorhexidine*, Nov. 5, 2009, available at <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5081492> ("Also, in an e-mail from OGC (via NOP) on March 24, 2009, it was stated: "In terms of the board recommending a substance to be added to the national list without a petition, (An OGC person sees) nothing in the OFPA or NOP regulations that would prohibit such action. (Another OGC person) agrees as well, and indicated that he believes the original NL was created by the board without any petitions. In either event, it would seem like the board's primary function is to make recommendations concerning the NL (to add, remove, renew, etc.) and that petitions are just one mechanism through which the board can make such recommendations.")

<sup>62</sup> EPA (2006) Reregistration Eligibility Decision (RED) for Coppers. page 33

per acre (lbs Cu<sup>2+</sup>/A) for filberts, RQs for nearly all sites exceeded the acute and chronic LOCs. Over 99% of the sites exceeded the acute LOC for invertebrates, and 80% exceeded for fish. Over 98% of the sites exceeded the chronic LOC for invertebrates and 44.9% exceeded for fish.

The percentage of sites for which RQs exceed the acute LOC is significantly less for typical rates more likely to be applied. The percentage of sites ranges from 3.2% at 1.0 lb Cu<sup>2+</sup>/A, and increases to about 25% of sites at an application rate of 7.5 lbs Cu<sup>2+</sup>/A. The RQs derived for freshwater fish with the BLM exceed the acute LOC for less than 1% of sites for application rates of 1.0 lb Cu<sup>2+</sup>/A and above.

The same exposure estimates translate into a greater number of sites exceeding the acute endangered species LOC of 0.05. As shown in Table 6 below, even at a rate of 1.0 lb Cu<sup>2+</sup>/A, aquatic RQs exceed that LOC in 19% of the 811 sites for freshwater invertebrates, while only exceeding the LOC for 1% of those sites for freshwater fish. The level of exceedence of the acute endangered species LOC for freshwater invertebrates and fish increases to 84% and 17%, respectively, based on an application rate of 7.5 lbs Cu<sup>2+</sup>/A.<sup>63</sup>

It can also harm other wildlife, since it is also classified as moderately toxic to birds and mammals.<sup>64</sup> The Environmental Protection Agency, in its Reregistration Eligibility Decision from 2006, states that copper can harm birds and mammals at currently allowed application rates in orchards and row crop fields.

Birds and orchard applications: “The highest label rate for orchard applications was for filberts (31.8 lbs Cu<sup>2+</sup>/A). At this application rate, all size classes of birds exceed the acute, acute endangered species, and chronic levels of concern for all food items.

“The highest average rate for orchard applications was for apples (3.8 lbs Cu<sup>2+</sup>/A). At this application rate, all size classes of birds exceed the endangered species acute risk LOC and the chronic risk LOC for all food items. Birds consuming the short grass, tall grass, and broadleaf plants food categories all exceed the acute risk and chronic risk LOCs, whereas with the fruit food item, larger birds and birds assessed with dietary-based endpoints are below the acute risk LOC.”<sup>65</sup>

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<sup>63</sup> EPA (2006) Reregistration Eligibility Decision (RED) for Coppers. page 38

<sup>64</sup> EPA (2006) Reregistration Eligibility Decision (RED) for Coppers. page 48

<sup>65</sup> EPA (2006) Reregistration Eligibility Decision (RED) for Coppers. page 50.

Birds and row crop applications: “The highest label rate for row crop applications was for potatoes (3.2 lbs Cu<sup>2+</sup>/A). At this application rate, all size classes of birds consuming the short grass, tall grass, and broadleaf plant food categories exceed the acute risk levels of concern. The small (20g) and medium (100g) birds consuming a diet of fruits, pods, seeds, or large insects exceed the acute risk LOC, using the dose-based calculation. All size classes of birds consuming all food types exceed the endangered species acute risk LOC and the chronic risk LOC.”

“The highest average rate for row crop applications was for potatoes (0.8 lb Cu<sup>2+</sup>/A). At this application rate, birds consuming the short grass, tall grass, and broadleaf plant categories exceed the endangered species acute risk LOC and the chronic risk LOC.”<sup>66</sup>

Mammals and orchard applications: “The highest labeled application rate for orchard use was for filberts at 31.8 lbs Cu<sup>2+</sup>/A, assuming four applications at weekly intervals. At this application rate, RQs for all size classes of mammals consuming plants or small insects exceed the acute risk, endangered species acute risk, and chronic risk LOCs. Except for 1,000g granivores, all size classes and food groups evaluated exceed the endangered species acute risk LOC.”<sup>67</sup>

Based on these hazards to aquatic life, the EPA requires the following Environmental Hazards Statement on pesticides for terrestrial uses containing copper compounds:

This pesticide is toxic to fish and aquatic invertebrates and may contaminate water through runoff. This product has a potential for runoff for several months or more after application. Poorly draining soils and soils with shallow water tables are more prone to produce runoff that contains this product. For terrestrial uses, do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash-waters or rinsate.

Certain water conditions including low pH (<6.5), low dissolved organic carbon (DOC) levels (3.0 mg/L or lower), and “soft” waters (i.e., alkalinity less than 50 mg/L), increases the potential acute toxicity to non-target aquatic organisms.

Drift and runoff may be hazardous to aquatic organisms in waters adjacent to treated areas.<sup>68</sup>

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<sup>66</sup> EPA (2006) Reregistration Eligibility Decision (RED) for Coppers. 2006 Page 51.

<sup>67</sup> EPA (2006) Reregistration Eligibility Decision (RED) for Coppers. 2006 Page 52.

<sup>68</sup> EPA (2006) Reregistration Eligibility Decision (RED) for Coppers. 2006 Page 86

A detailed discussion of the impact on beneficial insects is not included in the EPA's RED. Recent studies suggest there may be negative impacts on beneficial predatory insects.<sup>69</sup> Given the importance of beneficial predatory insects in organic farming systems, the potential of copper fungicides to disrupt balanced insect populations should be considered as well.

Copper is also highly toxic to soil invertebrates, including earthworms, in high concentrations and likely has negative effects at subacute levels as well.<sup>70 71</sup>

### **Compatibility with Organic Farming**

In addition to the impacts on earthworms, fish, birds and mammals, what are the impacts on soil health and fungus in the soil? Building healthy soil is a bedrock of organic farming. If organic farmers build the health of their soil, what effect do applications of copper have on this?

### **Conclusion**

We support the comments of the National Organic Coalition (NOC) on copper:

“We support renewing fixed coppers and copper sulfate on the National List while we simultaneously call for immediate, targeted research to identify management practices and less toxic alternative materials for addressing disease control for the wide range of crops produced by organic farmers.

“As the next step in this Sunset process, NOC urges the NOSB, in collaboration with its technical reviewers, to map the many combinations of crops and diseases for which organic farmers currently use copper as an integral part of their disease management systems. The outcome of that research should then be applied to a discussion about alternative disease management strategies that do not rely on the use of copper or other synthetic-based formulations.”

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<sup>69</sup> Martinou AF, Seraphides N, Stavrinides MC (2014) Lethal and behavioral effects of pesticides on the insect predator *Macrolophus pygmaeus*. Chemosphere 96:167-73. doi: 10.1016/j.chemosphere.2013.10.024.

<sup>70</sup> Bundy JG, Sidhu JK et al. (2008) 'Systems toxicology' approach identifies coordinated metabolic responses to copper in a terrestrial non-model invertebrate, the earthworm *Lumbricus rubellus* BMC Biol 6: 25. doi: [10.1186/1741-7007-6-25](https://doi.org/10.1186/1741-7007-6-25)

<sup>71</sup> Spurgeon DJ, Svendsen C et al (2005) Earthworm responses to Cd and Cu under fluctuating environmental conditions: a comparison with results from laboratory exposures. Environ Pollut.136(3): 443-52.

## ***7 CFR §205.601 - EPA List 4 - Inerts of Minimal Concern***

As a part of the National List, Consumer Reports believes that synthetic inert ingredients are required to meet all National List criteria, and we refer to our general policy comments concerning the need to apply National List criteria all substances on the National List, including inert ingredients. But beyond this issue, we would remind the NOSB of its intentions to address the underlying inconsistencies with the existing inert ingredient listing and move as expeditiously as possible in ensuring that OFPA standards are being upheld.

As all subcommittees are aware, the NOSB's released its formal recommendation on the subject of *Policy and Procedure on other "Inert" Ingredients in Pesticide Formulations on the NL* in 2012.<sup>72</sup> While the checkbox heading designated the recommended action for the NOP as a "Guidance Statement," the substance of the recommendation in fact asked for the NOP to "[r]eplace the language at sections 205.601(m) and 205.603(e) with the following language, including the listing of any approved (inert) ingredients, to be completed prior to the October 21, 2017 sunset date for List 4 inert,"<sup>73</sup> requiring a rulemaking action.

The recommended language to be inserted in 205.601(m) and 205.603(e) was the following:

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

- (i) Substances permitted for use in minimal risk products exempt from pesticide registration under FIFRA section 25(b);
- (ii) Reserved (for list of approved other ("inert") ingredients).<sup>74</sup>

The NOSB also provided several policy and procedure recommendations to accompanying the rulemaking.

Although we are aware that in order to accomplish this recommendation and the others put forward, the NOSB is dependent on the progress of the Inerts Working Group and

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<sup>72</sup> National Organic Standards Board, Formal Recommendation, *Policy and Procedure on other "Inert" Ingredients in Pesticide Formulations on the NL*, Oct. 16, 2012, <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5101281>.

<sup>73</sup> *Id.*

<sup>74</sup> *Id.*

NOP, the delay in accomplishing this necessary task no poses a significant issue concerning the sunset review of the inert ingredient listing.

For these reasons, we believe that the NOSB should make every effort to move forward with its work on the Inerts Working Group and place additional pressure on the NOP to move forward with the NOSB's proposed rulemaking, while also taking every step possible to uniformly apply the National List criteria to each synthetic inert ingredient.

We support the Crops Subcommittee in recommending an annotation to the inerts listing concerning Nonylphenol Ethoxylates (NPEs) and support the comments of NOC with regard to this effort, however, without expeditious action concerning all inert ingredient reviews, Consumer Reports does not believe the standards of organic on which consumers depend are being met.

We urge the NOSB to amend the inert substances listing to include a 2 to 3 year expiration date, so as to apply much needed pressure on the completion of the inert ingredient task force and NOP.

# LIVESTOCK SUBCOMMITTEE

## Petitions

### *Proposal: Methionine (MET)*

Based on a request from a petition, submitted in 2011 by the Methionine Task Force (MTF), the majority opinion of the Livestock Committee proposes to change the annotation of the methionine listing, from a maximum level to an average level of synthetic methionine in organic poultry feed. This would allow producers to increase the allowed levels above the current maximum levels at certain stages in the lives of laying hen chicks (when they first “come into production”).

Consideration of this petition is a carry-over from the Spring 2014 NOSB meeting, wherein it was recommended by the Livestock Committee to grant the petition, however, concerns were raised by the full NOSB as to whether the new sunset process would provide adequate pressure for development of organic alternatives without a mandatory expiration date.<sup>75</sup> After discussion by the full NOSB and it was determined that adding an expiration date would constitute a significant change from the subcommittee’s proposal and could not be accomplished during that meeting. The NOSB then decided to return the proposal subcommittee for consideration of an expiration date.

Unfortunately, the majority opinion of the Livestock Subcommittee for its Spring 2015 recommendation on methionine offers no consideration of an expiration date or evaluation of concerns over the lack of pressure imposed by the NOP’s Sunset Rule and revamped sunset process. Instead, the subcommittee opts for a resolution, stating that it is “committed to the phase-out of synthetic methionine for organic poultry production....” This is insufficient and as we noted in our 2014 comments, will not be effective in creating demand for natural methionine:

From the 2005 petition: “The intent of the NOSB was clear; Synthetic Methionine was not to be on the National List with the same status as other materials subject to renewal every five years. Nor was their intent to start a process that would damage or destroy the organic poultry industry. The intent with this material was to send a message that hard fast research would be required to find alternative feedstuffs and breeds. To source and develop the production of those alternatives and to seamlessly if not painlessly wean the US organic poultry industry from this last essential amino acid before the sunset.”

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<sup>75</sup> <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5107796>.

For the same reasons we opposed the Livestock Subcommittee's original proposal to adopt the averaging approach and relinquish the mandatory step-down, we oppose the majority subcommittee's proposal, especially without any effort to acknowledge the need for mandatory pressure points like expiration dates and step-down approaches. Averaging does not appear to be moving producers away from synthetic methionine use; rather, it allows the maximum levels to be higher than what they currently are in certain situations.

Consumer Reports opposes the continued use of synthetic methionine in poultry feed because it is inconsistent with OFPA's National List criteria and demonstrates a prime example of how the misapplication and misinterpretation of the National List criteria can create a never-ending exception to the organic standards on which consumers rely.

When materials like synthetic methionine do not sunset, and receive continued extensions, it sends a clear message to the marketplace that demand has been stunted and there is no real need to develop an alternative or, more importantly, shift production practices to be consistent with organic standards.

*Synthetic* methionine is not consistent with National List criteria for the following reasons:

- The production of synthetic methionine has harmful environmental impacts and is derived from toxic and harmful resources. Arguments that synthetic methionine benefits the environment by reducing nitrogen runoff overlook the fact that the same arguments are made for synthetic fertilizers on crops. Feeding systems that reduce levels of protein by using amino acid supplementation are not the only means identified to reduce nitrogen pollution from animal manure.<sup>76</sup> Consumers expect organic to not only avoid synthetic inputs, but also seek natural cropping and livestock raising methods that reduce environmental impacts.
- Synthetic methionine is not essential to the production of poultry because chickens can meet their nutritional needs if they are allowed to forage on well-managed pasture. Before the 1950s, chickens were raised without synthetic methionine.
- Synthetic methionine enables a system of poultry production that is not consistent with organic principles. It enables conventional raising practices, such as indoor confinement and rapid growth, in organics.
- Demeter biodynamic standards prohibit synthetic methionine in poultry production. A representative of Demeter clarified that certified farmers ensure that nutritional needs

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<sup>76</sup> <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5098033>.

are met by allowing the birds to forage on pasture (Demeter standards require that at least 50% of feed must come from on-farm production), and supplementing with natural sources of protein such as fermented dairy. Demeter standards set a minimum age of slaughter, thus eliminating the need for rapid growth.

- Synthetic methionine creates inconsistent requirements for different classes of organic producers. Setting aside the fact that organic livestock are supposed to receive 100% organic feed—a higher standard than that required for human consumption—pasture and growth requirements for other types of livestock, specifically cattle, will lead to reduced stocking densities and expanded land requirements to meet pasturing standards. Yes, this increases costs, but it is what consumers pay for when they buy organic.

For these reasons, every effort should be made to move methionine off the National List and not grant petitions that continue its use and place no pressure the industry to develop alternatives and better poultry standards. To accomplish this we urge the NOSB to adopt one of the two options provided in the minority opinion AND to establish a three-year expiration date.

### ***Proposal: Acidified Sodium Chlorite (ASC)***

We support the Livestock Subcommittee in its recommendations concerning the petitioned substance: Acidified Sodium Chlorite (ASC). The committee's review shows that this substance does not meet any of the National List criteria and should therefore not be included in on the National List.

### ***Proposal: Zinc Sulfate***

Consumer Reports recognizes that foot rot in livestock can pose serious health concerns and threats to herds. Zinc sulfate has been petitioned for inclusion on the National List for use in controlling foot rot, however, we continue to have reservations about the compatibility of zinc sulfate with organic production and its potentially harmful environmental impacts.

In particular, we do not feel enough information has been presented concerning several key questions:

- What are the conditions that give rise to foot rot? Are these conditions avoidable through organic production practices or consistent with organic production?
- Is foot rot more prevalent in large scale confinement operations?

- Does zinc sulfate treat foot rot or just act as a preventative? If a preventative, could prevention be achieved through stronger organic livestock welfare standards?

We support the Livestock Subcommittee's restraint in evaluating the petition for use of zinc sulfate and asking for more information on alternative treatments, however, as outlined by our questions above, we believe that further inquiry is needed into the systems that give rise to foot rot and assessing the compatibility of those systems with organic standards. Only after a broader look at what kind of livestock practices give rise to the problem of foot rot can the NOSB accurately assess all of the National List criteria.

## **Discussion Document: Aquaculture Legacy Document**

Consumer Reports continues to support the NOSB's decision to table any proposals concerning aquaculture inputs until the NOP releases defined organic aquaculture standards. We also support the efforts of the Livestock Subcommittee to develop some institutional memory and frame of reference for future NOSB members and the public.

Other consumer groups and stakeholders in the organic community, however, have raised some important points and facts to add to the Aquaculture Institutional Memory and we encourage the NOSB to review the expanded recommendations and incorporate them into the record. For reference, here is a summary of the points we believe should be incorporated or noted:

Membership and affiliations should be documented concerning all tasks forces and working groups. The inclusion of these membership lists in the institutional memory document provides essential information about the strong influence of the conventional aquaculture industry in producing reports and recommendations to the NOSB on key issues affecting aquaculture standards development. They further demonstrate the absence of the full spectrum of stakeholders in the aquaculture workgroups, and in the drafting of key documents that drove the development of NOSB recommendations and that formed the basis of impending organic aquaculture regulations.

Identify critical Areas of Disagreement Between Workgroups and the Public. The aquaculture standards proposed by the industry-led working groups included the use of wild caught fish as feeds and open ocean facilities. Both issues were strongly opposed by a majority of the organic community and this stakeholder input is an important part of the standards history.

Incorporate comments and positions of the public. The public has regularly and repeatedly stated at every NOSB meeting at which organic aquaculture has been on the agenda, that open ocean fish farms and the use of wild-caught fish for oil and meal in feed do not meet the requirements of organic certification and are inherently unfair to and

inconsistent with the producers who do meet organic requirements. Public comments have also consistently expressed opposition to organic certification for the farming of migratory fish species, such as salmon and consistently voiced support for greater research into the potential of land-based, inland, closed-loop, recirculating systems to raise certain fish species as certified organic. This is supported by Consumer Reports survey data which show the overwhelming majority of consumers think federal standards for organic fish should require that: (1) 100 percent organic feed is used (84%), (2) no antibiotics or other drugs are used (82%), and (3) no colors are added (81%). A sizable portion of consumers (67%) want federal standards to also include that no fish net pens are used.<sup>77</sup>

Consumer Reports remains concerned with the previous Board recommendations regarding aquaculture, and strongly urge the Board to reconsider them. We believe that open-net systems should be prohibited, wild-caught fish meal and fish oil should be prohibited and 100% organic feed should be required. Migratory fish that cannot migrate should not be produced in “organic” aquaculture systems. We plan to hold NOP and USDA accountable for establishing sound, consistent and meaningful organic aquaculture standards or to forgo establishing any.

## **Sunset - General**

We refer the NOSB to our general policy comments concerning sunset review and the changes imposed by the NOP, which we believe undermine the organic label and consumers expectations concerning exceptions to organic standards.

## **Sunset 2017 Sunset Summaries Meeting 1**

### ***7 CFR 205.603 - Chlorine Materials: Calcium hypochlorite, chlorine dioxide, sodium hypochlorite***

Consumer Reports recognizes that chlorine materials pose a difficult challenge in organic production context. On the one hand, chlorine is a readily available and effective disinfectant, often viewed as important in meeting food safety standards through all categories of its use (crops, handling, and livestock). However, the production, use, and disposal of chlorine have many documented negative human and environmental health effects, and its use overall is not consistent with organic production standards. While alternative sanitizers and disinfectants—both natural and synthetic on the National List—exist, there remain issues with the supply and demand for wholly natural substitutes.

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<sup>77</sup> Consumer Reports National Research Center, *Organic Food Labels Survey: 2014 Nationally-Representative Phone Survey* 1,016 adult U.S. Residents, March 2014, p. 5, available at <http://www.greenerchoices.org/pdf/CR2014OrganicFoodLabelsSurvey.pdf>.

As we have noted from the outset of these comments, adherence to the standards of organic and National List criteria must be at the forefront of every National List determination. In its past decisions on chlorine, the NOSB took great caution to include the material on National List with a limiting annotation under each of its categories. For use on livestock, the use restriction read:

Chlorine materials - disinfecting and sanitizing facilities and equipment.  
Residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.<sup>78</sup>

The intention behind this annotation and others was to limit chlorine's health and environmental impacts to those established for drinking water, thus better aligning chlorine with the National List criteria.

As a member of NOC, Consumer Reports is united in NOC's concern about the NOP clarification on the use of chlorine,<sup>79</sup> which allows for a higher concentration than allowed in the Safe Water Drinking Act, to be used in wash tanks, especially for organic food products that could absorb this higher concentration of chlorine into the food. Neither NOC nor Consumer Reports believe this clarification was the intent of the NOSB and is not consistent with OFPA National List criteria. Poultry, eggs, leafy vegetables, root crops and more could absorb highly chlorinated water and the final effluent after the wash tank could still only contain the required 4 PPM.

Consumer Reports supports the recommended annotation proposed by NOC to address this concern, but also recognizes the need to preserve disinfecting and sanitization needs for individual application. The annotation as presented by NOC reads:

Chlorine materials, only present as residual chlorine levels in water delivered by municipal or other public water systems, which shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.

- (i) Calcium hypochlorite.
- (ii) Chlorine dioxide.
- (iii) Sodium hypochlorite.

We recommend that this annotation be a foundational standard, but that individual applications and uses be included in the listing where necessary for sanitary purposes. In

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<sup>78</sup> 7 C.F.R. § 205.603.

<sup>79</sup> U.S. Dept. of Agriculture, Guidance: The Use of Chlorine Materials in Organic Production and Handling, NOP 5026, July 22, 2011, available at <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5090760>

setting those individual application annotations, we support NOC's recommendations that the following additional factors considered:

The use of chlorine on food contact surfaces should be handled separately from the use of dissolved chlorine in tank situations, especially on foods that can absorb some of the wash water.

To be consistent, the use of other approved disinfectant products in wash tank water systems should also be reviewed as to the possibility of absorption, at what concentration, and any negative health effects. This would include peracetic acid.

Based partly on the efforts of EPA's Design for the Environment results, prioritize research on a variety of cleaning and disinfection materials for use in organic food processing, especially those that would be readily available, at a reasonable price and effective in a variety of situations. Moreover, EPA's DFE does not allow chlorine products to be used for disinfection further documenting its incongruence with organic standards.

We recognize that because the NOSB has been banned from annotating National List materials during the sunset review process, these recommendations may pose a logistical issue. Accordingly, we propose that the NOSB make every effort to bring forward its own parallel proposal, addressing these concerns.<sup>80</sup>

Just because chlorine is on the National List and the NOP has offered misguided interpretations of the NOSB's efforts to ensure that National List materials align with OFPA criteria does not mean that the NOSB should surrender its well-founded intentions. For chlorine's use to continue to meet the necessary OFPA National List criteria, we strongly urge the NOSB to consider whatever means are possible to make the suggested annotations and clarifications.

### ***7 CFR 205.603 - EPA List 4 - Inerts of Minimal Concern***

As a part of the National List, Consumer Reports believes that synthetic inert ingredients are required to meet all National List criteria, and we refer to our general policy comments concerning the need to apply National List criteria all substances on the

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<sup>80</sup> See, e.g., National Organic Standards Board, Formal Recommendation by the National Organic Standards Board (NOSB) to the National Organic Program (NOP), *Chlorhexidine*, Nov. 5, 2009, available at <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5081492> ("Also, in an e-mail from OGC (via NOP) on March 24, 2009, it was stated: "In terms of the board recommending a substance to be added to the national list without a petition, (An OGC person sees) nothing in the OFPA or NOP regulations that would prohibit such action. (Another OGC person) agrees as well, and indicated that he believes the original NL was created by the board without any petitions. In either event, it would seem like the board's primary function is to make recommendations concerning the NL (to add, remove, renew, etc.) and that petitions are just one mechanism through which the board can make such recommendations.")

National List, including inert ingredients. But beyond this issue, we would remind the NOSB of its intentions to address the underlying inconsistencies with the existing inert ingredient listing and move as expeditiously as possible in ensuring that OFPA standards are being upheld.

As all subcommittees are aware, the NOSB's released its formal recommendation on the subject of *Policy and Procedure on other "Inert" Ingredients in Pesticide Formulations on the NL* in 2012.<sup>81</sup> While the checkbox heading designated the recommended action for the NOP as a "Guidance Statement," the substance of the recommendation in fact asked for the NOP to "[r]eplace the language at sections 205.601(m) and 205.603(e) with the following language, including the listing of any approved (inert) ingredients, to be completed prior to the October 21, 2017 sunset date for List 4 inert,"<sup>82</sup> requiring a rulemaking action.

The recommended language to be inserted in 205.601(m) and 205.603(e) was the following:

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

- (i) Substances permitted for use in minimal risk products exempt from pesticide registration under FIFRA section 25(b);
- (ii) Reserved (for list of approved other ("inert") ingredients).<sup>83</sup>

The NOSB also provided several policy and procedure recommendations to accompanying the rulemaking.

Although we are aware that in order to accomplish this recommendation and the others put forward, the NOSB is dependent on the progress of the Inerts Working Group and NOP, the delay in accomplishing this necessary task no poses a significant issue concerning the sunset review of the inert ingredient listing.

For these reasons, we believe that the NOSB should make every effort to move forward with its work on the Inerts Working Group and place additional pressure on the NOP to

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<sup>81</sup> National Organic Standards Board, Formal Recommendation, *Policy and Procedure on other "Inert" Ingredients in Pesticide Formulations on the NL*, Oct. 16, 2012, <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5101281>.

<sup>82</sup> *Id.*

<sup>83</sup> *Id.*

move forward with the NOSB's proposed rulemaking, while also taking every step possible to uniformly apply the National List criteria to each synthetic inert ingredient.

We support the Crops Subcommittee in recommending an annotation to the inerts listing concerning Nonylphenol Ethoxylates (NPEs) and support the comments of NOC with regard to this effort, however, without expeditious action concerning all inert ingredient reviews, Consumer Reports does not believe the standards of organic on which consumers depend are being met.

## **Other issues - Workplan**

### ***Poultry Genetics***

We believe there is a need in the organic standards for a requirement preventing the use of poultry breeds and strains that have been selected for rapid growth, which comes at the expense of bird health and welfare.

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

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

In the European Union, organic standards require a minimum age at slaughter to prevent the use of rapidly growing strains. Label programs in the US, 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 urge the Livestock Subcommittee to add this topic to its workplan.

### ***Antibiotics in organic poultry production***

In December 2013, we sent a letter<sup>84</sup> to Secretary Vilsack urging the USDA to prohibit the administration of antibiotics to day-old organic chicks, as well as chicks still in the egg.

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<sup>84</sup> <http://www.greenerchoices.org/products.cfm?product=0114organicloophole&pcat=food>

“Organic” is widely marketed to consumers as meaning “no antibiotics.” Yet while the standards expressly prohibit any animal treated with antibiotics to be sold, labeled or represented as “organic” (see 7CFR205.238(c)(1)), the organic law (section 6509(e)(1)) and standards (7CFR205.236(a)(1)) exempt day-old chicks from organic management.

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

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

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

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

We urge the NOSB to add its voice of support to a rule change that would prohibit antibiotics in organic poultry production, at all stages of production, and eliminate the last remaining exception for antibiotic use in organic production.

## **CONCLUSION**

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

Sincerely,

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