

October 11, 2016

Ms. Michelle Arsenault National Organic Standards Board USDA-AMS-NOP 1400 Independence Ave., SW Room 2648-S, Mail Stop 0268 Washington, DC 20250-0268

Re. MS: Research Priorities

These comments to the National Organic Standards Board (NOSB) on its Fall 2016 agenda are submitted on behalf of Beyond Pesticides. Founded in 1981 as a national, grassroots, membership organization that represents community-based organizations and a range of people seeking to bridge the interests of consumers, farmers and farmworkers, Beyond Pesticides advances improved protections from pesticides and alternative pest management strategies that reduce or eliminate a reliance on pesticides. Our membership and network span the 50 states and the world.

Except as noted below, Beyond Pesticides supports all of the research priorities brought forth by the Materials Subcommittee. We have a few comments on specific topics and the general procedure below.

Comments on Specific Topics

We urge that the comments below strengthen the call for research on these issues. to broaden its outreach, as recommended by the NOSB in establishing this annual proposal of research priorities, to include "private foundations and other funders." NOP should also report back to the NOSB about its outreach efforts during this annual consideration of research priorities.

Chlorine Materials and Alternatives

We support a comprehensive review of all sanitizers, disinfectants, cleansers, and their uses by the NOSB. The review of individual materials in accordance with OFPA criteria cannot be performed in a vacuum. We cannot <u>assume</u> a need and efficacy for any and all antimicrobial materials. The need for such materials and their efficacy must be established. In particular, the need for the most hazardous materials should be established in light of less hazardous materials and practices that can meet the needs of organic producers and handlers.

Thus, the goal of a comprehensive review is to identify the needs of organic producers and

handlers —"needs" that might be established by law or by the requirement to reduce certain microbial populations. In view of the growing body of research showing the importance of a balanced microbiome in and on our bodies, food, and the environment, it is rash to <u>assume</u> that sterility is needed. Therefore, a comprehensive review would start by identifying uses of sanitizers, disinfectants, and cleansers in organic production and handling, and determining to what extent they are (a) required by law or (b) required to meet an established limitation on microbial populations (or other standards). This comprehensive review would also consider which materials are available to meet these needs and their relative hazards. Additionally, the concept of hazard, in this context, must be expanded to evaluate cross-resistance with antibiotics and the public health threat associated with antibiotic resistance in the U.S. and worldwide.¹ OFPA requires this type of analysis, putting organic production and its allowed materials on the leading edge of protecting public health.

Therefore, the comprehensive review sets the stage for reviewing each sanitizer, disinfectant, and cleanser on the National List for each of its uses and its interaction with one of the most dramatic public health threats of our day, antimicrobial and antibiotic resistance. It would also help identify needs for newer, less hazardous, materials. This comprehensive review should also take advantage of the EPA's Safer Choice review of sanitizers.

The Handling Subcommittee has prioritized research on this issue. We are not sure that this issue meets the criteria for research priorities, given the documentation in the scientific literature that currently exists. In particular, this issue is not nebulous or lacking in primary research. We believe that a well-defined technical review is the appropriate step to take. While it is possible that topics requiring more research will arise in the process of this review, the subcommittee should proceed with a technical review.

Celery Powder

We believe that an attempt to grow organic celery in a way that is high in nitrates in order to subvert the prohibitions in OFPA is incompatible with organic production and produces unhealthy organic food. Lower levels of nitrates are often mentioned as a reason for judging organic food to be more healthful.²

Given the known health effects of nitrates, there is no good reason for encouraging the use of celery powder as a nitrate source in food. ATSDR/CDC lists, for example, methemoglobinemia,

¹ The research on antibiotic resistance and horizontal gene transfer (as was explained to the board by the Infectious Diseases Society of America) was discussed at length by the NOSB during debates on tetracycline and streptomycin. See the NOSB recommendations for extensive citations. International concern over the health threat posed by resistance to antimicrobials was shown recently when the United Nations general assembly convened to address the alarming rise of antibiotic resistance at a day-long meeting in New York. See their declaration: http://www.un.org/pga/71/wp-content/uploads/sites/40/2016/09/DGACM_GAEAD_ESCAB-AMR-Draft-Political-Declaration-1616108E.pdf.

² See, for example, Lima, G.P. and Vianello, F., 2011. Review on the main differences between organic and conventional plant-based foods. *International Journal of Food Science & Technology*, 46(1), pp.1-13.

hypotension, risk of pregnancy complications, a number of reproductive effects, and cancer, among others. Regarding cancer, ATSDR says:³

Some study results have raised concern about the cancer-causing potential of nitrates and nitrites used as preservatives and color-enhancing agents in meats [Norat et al. 2005; Tricker and Preussmann 1991]. Nitrates can react with amino acids to form nitrosamines, which have been reported to cause cancer in animals [Bruning-Fann and Kaneene 1993]. Elevated risk of non-Hodgkin's lymphoma [Ward et al. 1996] and cancers of the esophagus, nasopharynx, bladder, colon, prostate and thyroid have been reported [Cantor 1997; Eichholzer and Gutzwiller 1998; Barrett et al. 1998; Ward et al. 2010].

An increased incidence of stomach cancer was observed in one group of workers with occupational exposures to nitrate fertilizer; however, the weight of evidence for gastric cancer causation is mixed [Van Loon et al. 1998; Xu et al. 1992]. Epidemiological investigations and human toxicological studies have not shown an unequivocal relationship between nitrate intake and the risk of cancer [Alexander et al. 2010; Mensinga et al. 2003].

The International Agency for Research on Cancer (IARC) classifies nitrates and nitrites as "probably carcinogenic to humans" (Group 2A) under certain conditions (i.e. ingested nitrate or nitrite under conditions that result in endogenous nitrosation) which could lead to the formation of known carcinogens such as N-nitroso compounds [IARC 2010].

Finally, recent work demonstrates serious hormonal impacts of nitrate exposure.⁴

OFPA §6510(a)(2)-(3) makes it illegal to:

- (2) add any ingredient known to contain levels of nitrates, heavy metals, or toxic residues in excess of those permitted by the applicable organic certification program;
- (3) add any sulfites, except in the production of wine, nitrates, or nitrites;

The regulations at §205.301(f)(5) state that organic products must not "Contain sulfites, nitrates, or nitrites added during the production or handling process, Except, that, wine containing added sulfites may be labeled "made with organic grapes."

Celery powder is used in such a way that it adds significant nitrite, in light of the following.

Celery powder prepared from celery juice has been shown to have a nitrate content of approximately 2.75%. When using juice powder added at 0.2%, 0.35%, or 0.4% (on a total formulation basis), and assuming 100% nitrate-to-nitrite conversion, ingoing nitrite

³ http://www.atsdr.cdc.gov/csem/csem.asp?csem=28&po=10.

⁴ Guillette, L. J., & Edwards, T. M. (2005). Is nitrate an ecologically relevant endocrine disruptor in vertebrates?. *Integrative and Comparative Biology*, *45*(1), 19-27.

Guillette, L. J. (2006). Endocrine disrupting contaminants-beyond the dogma. *Environmental health perspectives*, 114, 9.

concentrations of approximately 69, 120, and 139 ppm (based on meat block), respectively, could be expected. As the amount of celery juice powder in the formulation increases, higher amounts of generated nitrite can be expected. ...From these results it was determined an uncured product with nitrite replaced with a source containing naturally occurring nitrate could result in a product with higher levels of residual nitrite than one in which nitrite was originally and intentionally added.⁵

The concentrations above should be compared to the limit of 10 ppm in drinking water and the European Commission's (EC) Scientific Committee for Food (SCF) Acceptable Daily Intake (ADI) for the nitrate ion of 3.65 mg/kg body weight (equivalent to 219 mg/day for a 60 kg person).

It would therefore be more appropriate to focus research on achieving the ends provided by nitrate in a different way.

Alternatives to Bisphenol A

Again, we suggest a technical review on packaging substances used in organic food handling with bisphenol A (BPA) as a logical first step in identifying organic compatible packaging. This may be an area with which the NOSB is unfamiliar, but that does not mean that primary research is not available. Before proposing this topic as a research priority, the NOSB should commission a technical review of the current literature. Since Beyond Pesticides has a long history of concern about endocrine-disrupting chemicals, and BPA is a well-known endocrine disruptor, 6 we offer some resources connected to that investigation.

See The Endocrine Disruption Exchange (TEDX) projects on Bisphenol A (http://endocrinedisruption.org/endocrine-disruption/bisphenol-a/overview).

For information on some substitutes that are also endocrine disruptors, see: Rochester JR, Bolden AL. Bisphenol S and F: A Systematic Review and Comparison of the Hormonal Activity of Bisphenol A Substitutes. *Environ Health Perspect*; http://dx.doi.org/10.1289/ehp.1408989.

⁵ Ingredients in Meat Products: Properties, Functionality and Applications. pp. 398–399.

⁶ Ho SM, Tang WY, De Frausto JB, Prins GS. 2006. Developmental exposure to estradiol and bisphenol A increases susceptibility to prostate carcinogenesis and epigenetically regulates phosphodiesterase type 4 variant 4. Cancer Res 66(11):5624-5632.

Kubo K, Arai O, Omura M, Watanabe R, Ogata R, Aou S. 2003. Low dose effects of bisphenol A on sexual differentiation of the brain and behavior in rats. Neurosci Res 45(3):345-356.

Murray TJ, Maffini MV, Ucci AA, Sonnenschein C, Soto AM. 2007. Induction of mammary gland ductal hyperplasias and carcinoma in situ following fetal bisphenol A exposure. Reprod Toxicol 23(3):383-390.

Timms BG, Howdeshell KL, Barton L, Bradley S, Richter CA, vom Saal FS. 2005. Estrogenic chemicals in plastic and oral contraceptives disrupt development of the fetal mouse prostate and urethra. Proceedings of the National Academy of Sciences USA 102(19):7014-7019.

Wadia PR, Vandenberg LN, Schaeberle CM, Rubin BS, Sonnenschein C, Soto AM. 2007. Perinatal bisphenol A exposure increases estrogen sensitivity of the mammary gland in diverse mouse strains. Environ Health Perspect 115(4):592-598.

This review was carried out to evaluate the physiological effects and endocrine activities of the BPA substitutes BPS and BPF. It compared the hormonal potency of BPS and BPF to BPA. Based on 32 studies to date (25 *in vitro* only, and seven *in vivo*), the majority of studies found the potency of BPS and BPF to be in the same order of magnitude and of similar action to BPA (estrogenic, anti-estrogenic, androgenic, and anti-androgenic) *in vitro* and *in vivo*. BPS also has potencies similar to estradiol in membrane-mediated pathways, which are important for cellular actions like proliferation, differentiation, and death. BPS and BPF also showed other effects *in vitro* and *in vivo*, such as altered organ weights, reproductive endpoints, and enzyme expression. The authors concluded that BPS and BPF are as hormonally active as BPA, and have endocrine disrupting effects.

As the above-cited article indicates, not all alternatives to BPA are free from endocrine-disrupting effects. The TR contractors should search the TEDX database (http://endocrinedisruption.org/endocrine-disruption/tedx-list-of-potential-endocrine-disrupting properties of chemicals.

Consumer Demand

Frankly, we find the presentation on this issue to lack respect for the importance of the consumer voice in organic policy making and standard setting, and thus undermining of a key element in the sustained growth of the organic sector. Many of the nonprofit organizations that testify at NOSB meetings include organic consumers among their membership and networks. One of the organizations presenting information about consumer expectations is Consumer Reports/Consumers Union, which is widely respected for its surveys of consumers of a wide variety of products. A failure to appreciate the importance of the organizations that bring their consumer constituency voice to the NOSB's deliberations will harm the integrity of organic.

The HS asks, "Is there a better measure of consumer preference and expectations for organic products than sales figures?" Sales are only as good as the choices and information provided to consumers, and surveys can provide information about what consumers <u>would do</u> given more choices and more information.

Comments on General Procedure

The spring 2012 NOSB recommendation that established a framework for these annual recommendations of research priorities advised that NOP share them with "private foundations and other funders" as well as USDA programs. Some non-governmental organizations do report to the NOSB that they are glad to receive these recommendations. We suggest that the NOSB request NOP to broaden its scope in delivering the priorities and also request an annual report from NOP on how it has distributed the research priorities.

Thank you for your consideration of these comments.

Sincerely,

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Terry Shistar, Ph.D. Board of Directors