National Organic Standards Board
Handling Subcommittee
Bisphenol A (BPA) in Packaging Discussion Document

February 21, 2017

I. INTRODUCTION

The National Organic Standards Board (NOSB) initiated a work agenda item for evaluating packaging materials in 2013. At this time, the Handling Subcommittee (HS) has decided to proceed with a discussion document to collect input from organic stakeholders on this issue while an independent technical report is in process.

Bisphenol A (BPA) is a chemical widely used in manufacturing polycarbonate plastics and epoxy resins used in many industries, including the lining of cans for food. Releases of BPA to the environment exceed 1 million pounds per year (EPA, 2010). It is a known endocrine disruptor, and several studies and biomonitoring programs demonstrate that BPA leaches out of the linings of cans used for food and that human populations are widely exposed (EPA, 2010). For example, BPA was frequently detected in participants in U.S. CDC and California biomonitoring programs (CDC; State of California 2017a) and studies worldwide (Vandenberg LN et al., 2010). Several studies indicate that food contact materials are a primary source of BPA exposure in humans (Carwile et al., 2011; Rudel et al. 2011). For example, in 2011, researchers at the Harvard School of Public Health determined that volunteers who ate a single serving of canned soup a day for five days had ten times the amount of BPA in their bodies as when they ate fresh soup daily (Carwile et al., 2011). Several studies suggest BPA may be harmful to human health at low exposure levels (Sowlat et al., 2016, Rochester JR, 2013, Ejaredar M, 2016) and it is listed as a chemical known to be a reproductive toxicant under the California Safe Drinking Water and Toxic Enforcement Act (State of California 2015).

BPA is currently allowed for use in cans and other packaging containing organic food. In the interest of organic integrity for processed foods, the NOSB is reviewing concerns about BPA in the same way that other synthetic materials that come into contact with organic food are evaluated.

While some organic processors have found alternatives to BPA in their products, the NOSB does not have information on how much BPA is still used in organics and whether alternative packaging materials are widely used. The NOSB would also like to know more about what alternatives to BPA are being used and if any of the alternative materials might raise human health concerns. The Handling Subcommittee and most organic consumers agree that organic food should be produced in a manner that minimizes exposure to toxic materials in any form. Therefore, this discussion document will alert stakeholders to this issue and begin information gathering to determine whether changes are needed in the regulations to ensure harmful substances do not come into contact with organic food.

II. BACKGROUND

In December 2013 a request was submitted by the NOSB Handling Subcommittee to the National Organic Program to add the issue of BPA in packaging to the NOSB work agenda. In November 2014 the NOP issued a Memorandum to the NOSB, titled "*Packaging substances used in organic food handling"*, in which the NOP acknowledged the request and that there were recent studies that raised concern about BPA and similar packaging substances. They suggest:

> "That NOSB start with a discussion paper that provides a review of current literature, evaluation of current uses in the organic market, availability and suitability of alternatives, and impact of removal of these packaging substances on the organic trade."

The memorandum was accompanied by a letter from Senator Dianne Feinstein that supports a ban on BPA.

Additionally, several public comments addressing plastics and BPA were submitted in 2015 and 2016. These comments raised human health and environmental concerns about the use of plastic packaging for organic foods, and many specifically focused on BPA.

A request for a Technical Report (TR) was submitted in August 2015. The following specific issues were posed to the writers of the TR:

- "There is much criticism by both sides of the BPA safety debate over the validity of various research methods, from what breed of rats are used to human cell studies in vitro vs. animal studies. There are also collusion, conflict of interest, and bias contentions in some research efforts. Please examine these objectively using the citations below and others, and give an evaluation of which research is the most valid.
- Evaluate the conclusion from the paper by Yang cited above that they can identify existing compounds, additives, or processing agents that have no detectable estrogenic activity and have similar costs. What are these alternatives?
- Review recent research on some of the BPA alternatives in use, such as Tritan (containing triphenyl phosphate or TPP), Bisphenol S (BPS) and Bisphenol F (BPF) and any others. Some citations are below.
  What is the status of BPA in other countries? How widespread are bans on BPA and are any of the alternatives banned as well? What evidence was used in making those determinations?"

The NOP contracted for the TR in January 2016 with the Agricultural Analytics Division of the USDA AMS. The TR was provided to the NOSB on October 19, 2016. In December of 2016 the HS determined that the report was technically insufficient according to the criteria in the NOSB PPM. In response, NOP issued another statement of work to externally contract this work and OMRI received the award for BPA. The OMRI report is currently in development.

III. RELEVANT AREAS OF THE RULE

§205.272 Commingling and contact with prohibited substance prevention practice standard.

(a) The handler of an organic handling operation must implement measures necessary to prevent the commingling of organic and nonorganic products and protect organic products from contact with prohibited substances.

(b) The following are prohibited for use in the handling of any organically produced agricultural product or ingredient labeled in accordance with subpart D of this part:

(1) Packaging materials, and storage containers, or bins that contain a synthetic fungicide, preservative, or fumigant;

(2) The use or reuse of any bag or container that has been in contact with any substance in such a manner as to compromise the organic integrity of any organically produced product or ingredient placed in those containers, unless such reusable bag or container has been thoroughly cleaned and poses no risk of contact of the organically produced product or ingredient with the substance used.

IV. DISCUSSION

In this discussion the NOSB Handling Subcommittee is seeking information from the industry on several points, including whether BPA should be prohibited and how widespread BPA is used in organic foods.

The HS would also like to collect information on the factors that affect the choice of alternatives and what those alternatives are. This information will be considered along with the final TR when it is publically available.

A. Should BPA be prohibited?

A concise summary of the situation regarding BPA is described in the Environmental Protection Agency BPA Action Plan (EPA, 2010).

> "Because BPA is a reproductive, developmental, and systemic toxicant in animal studies and is weakly estrogenic, there are questions about its potential impact particularly on children's health and the environment. Studies employing standardized toxicity tests used globally for regulatory decision-making indicate that the levels of BPA in humans and the environment are below levels of potential concern for adverse effects. However, results of some recent studies using novel low-dose approaches and examining different endpoints describe subtle effects in laboratory animals at very low concentrations. Some of these low-dose studies are potentially of concern for the environment because the concentration levels identified with effects are similar to some current environmental levels to which sensitive aquatic organisms may be exposed.
>
> Regulatory authorities around the world reviewing these low-dose studies have generally concluded that they are insufficient for use in risk assessment because of a variety of flaws in some of the study designs, scientific uncertainty concerning the relevance to health of the reported effects, and the inability of other researchers to reproduce the effects in standardized studies. However, since the low-dose studies do raise questions and concerns, some authorities have taken action to protect sensitive populations, particularly infants and young children."

The latest review from the Food and Drug Administration, published in June 2014 (FDA, 2014), reviewed all the literature since the previous review in 2008:

> "The conclusion of this report is that an adequate margin of safety exists for BPA at current levels of exposure from food contact uses."

FDA also note that there is significant uncertainty associated with extrapolating safety data obtained from rodents and non-mammalian chordates to primates (including humans) because there is a decreased capacity of non-primates to metabolize BPA and there have been large variability in study results.

On the other hand, scientific articles are being published regularly that show that low doses of BPA may be more harmful than higher doses, and that these troubling results are resulting from well conducted research (Johns et al. 2016, Kinch et al. 2015, Science Daily).

For example, human epidemiological studies have shown associations between BPA and a number of adverse outcomes on child behavior, metabolic disorders, and fertility, among other outcomes. Additionally, in 2015 BPA was listed as a chemical known to the state of California to cause reproductive toxicity (Rochester 2013, Johns et al. 2016, Sowlat et al. 2016, Ejaredar et al. 2016, State of California 2015).

There are also concerns about two of the main alternatives to BPA: BPS and BPF. For example, BPS and BPF share similar chemical structures with BPA and may have estrogenic activity and act by similar mechanisms (Hashimoto et al. 2001, Rochester and Bolden 2015, Chen 2002, Kinch et al. 2015).

Individual epidemiologic studies are observational and therefore cannot show causation. However, human studies are most relevant to inform our understanding of human health risks, and a growing

literature suggests that BPA may adversely impact human health, potentially at environmentally relevant levels. Finally, as described above, there is evidence of widespread human exposure with food packaging materials as a primary exposure source.

In summary, as evidence of negative effects on health builds and organic consumers raise concerns about their food choices, evaluation of BPA and similar chemicals by the NOSB is warranted.

B. How much BPA is in use in organic food?

Many, but not all, organic brands have removed BPA from food contact materials (http://www.ewg.org/research/bpa-canned-food). Also, very few companies label their cans as not having BPA so it is hard for consumers to make informed decisions from food labels. A report from the Environmental Working Group provides some information on BPA substitutes used in canned food (EWG, 2015). However, there does not appear to be any independent testing to verify that cans are BPA free. The state of California is developing a database of canned products containing BPA (State of California 2017b), but this data set has not been evaluated in relation to organic products. In summary, more information is needed before the NOSB can make a decision.

C. What alternative materials and practices are being used by organic processors and what factors are prohibiting more products from using alternatives?

- There are can coatings that do not contain epoxy resins, such as those with polyester.
- Baked organic coatings have been used in cans, including oleoresinous, epoxy-amine, and acrylic enamel coatings. Oleoresinous coatings are made from vegetable oil and resin (Deshpande 1995).
- Glass jars are a good alternative although there may still be BPA used in the sealing ring under the lid.
- More BPA migrates from the can lining into the food at higher temperatures and over longer time sitting on the shelf. So processing at lower temperatures and not storing canned goods for long periods will lessen exposure. BPA leaching can also be minimized by increasing the curing time for coatings that contain it. It is not possible for consumers to find out if the curing of the cans for any individual brand was done correctly (Rossi et al. 1970, Lambert et al. 1998).
- Polyethylene and polypropylene packaging can be used instead of BPA cans. These are likely to have less estrogenic activity (Yang et al. 2011). Bioplastics from starch materials, cellulose materials, polylactic acid (Polyester, PLA), polyhydroxy acid (polyester, PHA) that are not only BPA free, but have melting points above 200^{o}C, good moisture barrier characteristics and good compostability and biodegradability properties are now in development (Siracusa et al., 2008) The bioplastics may be combined with nanoscale fillers such as layered silicate nanoclays, e.g. montmorillonite and kaolinite which may also have a role in effective and environmentally friendly food packaging (Rhim et al, 2013). Bioplastics may be problematic for organic food producers because they are often sourced from genetically modified corn. Currently there are no restrictions on these products.

V. REQUEST FOR PUBLIC COMMENT

The NOSB is requesting public comment from both companies who no longer use BPA in packaging, and from those who still think it is necessary. From the former group we would like to hear what is being used instead, and how well it is working. From the latter we would like to know what, if anything, has been tried and rejected, and why. Also, we would like to know reasons why it is still important for specific product categories to allow BPA in packaging. Specific questions include:

A. Should BPA be prohibited?
B. How widespread is the use of BPA in organic canned foods utilizing metal cans?

C. How widespread is the use of BPA in lids or other materials in contact with canned organic food in glass jars?
D. Is BPA present in any other packaging or processing materials that are in contact with organic food?
E. The California Office of Environmental Health Hazard Assessment has compiled a database of canned foods with BPA in metal can liners or jar lids: https://www.p65warnings.ca.gov/bpalist Is this database complete and have any members of the organic community examined this data to determine the prevalence of organic brands using BPA?
F. Are there specific product categories where BPA should be allowed if some uses, such as BPA in linings for canned foods, are prohibited?
G. What alternatives materials and practices have been chosen by organic processors and how well are they working?
H. Have any alternative materials been tried and rejected? If so, why?
I. What factors are prohibiting more products from using alternatives?
J. What are the human health and/or environmental concerns of BPA alternatives, such as BPS and BPF?

The NOSB welcomes comments on the use of BPA in food packaging. Please see https://www.ams.usda.gov/event/nosb-spring-2017-meeting-denver-co for information on how to submit written or oral comments for the Spring 2017 meeting.

Vote in Handling Subcommittee
Motion to accept the BPA discussion document
Motion by: Scott Rice
Seconded by: Lisa de Lima
Yes: 6 No: 0 Abstain: 0 Absent: 2 Recuse: 0

References

Carwile JL, Ye X, Zhou X, Calafat AM, Michels KB. 2011. Canned soup consumption and urinary bisphenol A: a randomized crossover trial. JAMA. [November 22, 2011].

Centers for Disease Control and Prevention (CDC), Biomonitoring Summary. https://www.cdc.gov/biomonitoring/BisphenolA_BiomonitoringSummary.html

Chen MY, Ike M, Fujita M. 2002. Acute toxicity, mutagenicity, and estrogenicity of bisphenol-A and other bisphenols. Environmental Toxicology. [February 2002]. (1):80-6.

Deshpande, AV. 1995. Agro based oleoresinous media for surface coatings. Chemical Engineering World, 30:2, pp.47-51

Ejaredar M, Lee Y, Roberts DJ, Sauve, R, Dewey D. 2016. Bisphenol A exposure and children's behavior: A systematic review. Journal of Exposure Science and Environmental Epidemiology. [March 2016]. doi: 10. 1038/jes.2016.8. https://www.ncbi.nlm.nih.gov/pubmed/26956939

Environmental Working Group, 2015. BPA in Canned Food: Behind the Brand Curtain. http://static.ewg.org/reports/2015/bpa_in_canned_food/BPA-in-canned-food.pdf?_ga=1.213061588.19053588.1483395763

Hashimoto Y, Moriguchi Y, Oshim, H, Kawaguchi M, Miyazaki K, Nakamura M. 2001. Measurement of estrogenic activity of chemicals for the development of new dental polymers, Toxicology in vitro, 15, pp. 421-425

Johns LE, Ferguson KK, Meeker JD. 2016. Relationship between urinary phthalate metabolite and bisphenol A concentrations and vitamin D levels in U.S. adults: national health and nutrition examination survey. The Journal of Clinical Endocrinology & Metabolism. [November 1, 2016]. 101 (11): 4062-4069.

Kinch CD, Ibhazehiebo K, Jeong JH, Habibi HR, Kurrasch DM. 2015. Low-dose exposure to bisphenol A and replacement bisphenol S induces precocious hypothalamic neurogenesis in embryonic zebrafish. Proceedings of the National Academy of Science of the United State of America. [February 2015]. 112(5):1475-80.

Lambert C, Larroque M, Teixido J, Gerard J-F. 1998. Food-contact epoxy resin: Co-variation between migration and degree of cross-linking. Part II, Food Additives & Contaminants, 15:3, pp. 318-328.

Rhim J-W, Park H-M, Ha C-S. (2013) Bio-nanocomposites for food packaging applications, Progress in Polymer Science, 38, pp. 1629– 1652

Rochester JR. 2013. Bisphenol A and human health: a review of the literature. Reproductive Toxicology (Elmsford, N.Y.). [December 2013]. 42:132-55 https://www.ncbi.nlm.nih.gov/pubmed/23994667

Rochester JR and Bolden AL 2015. Bisphenol S and F: a systematic review and comparison of the hormonal activity of bisphenol A substitutes, Environ. Health Perspect., 123, pp. 643–650

Rossi, AG, Charland, GA, Stammer, WC. 1970. Determining the cure parameters of can coatings, Journal of Paint Technology, 42:546, pp. 391-397.

Rudel RA, Gray JM, Engel CL, Rawsthorne TW, Dodson RE, Ackerman JM, Rizzo J, Nudelman JL, Brody JG. Food packaging and bisphenol A and bis(2-ethyhexyl) phthalate exposure: findings from a dietary intervention. Environ Health Perspect. 2011 Jul;119(7):914-20. doi: 10.1289/ehp.1003170. Epub 2011 Mar 30.

Science Daily. https://www.sciencedaily.com/search/?keyword=bpa#gsc.tab=0&gsc.q=bpa&gsc.page=1

Siracusa V, Rocculi R, Romani S, Rosa MD. 2008. Biodegradable polymers for food packaging: a review. Trends in Food Science & Technology, 19, pp. 634-643

Sowlat MH, Lotfi S, Yunesian M, Ahmadkhaniha R, Rastkari N. 2016. The association between bisphenol A exposure and type-2 diabetes: a world systematic review. Environmental Science and Pollution Research International. [November 2016]. 23(21):21125-21140. https://www.ncbi.nlm.nih.gov/pubmed/27650850;

State of California 2017a - http://biomonitoring.ca.gov/results/chemical/64

State of California 2015 – Office of Environmental Health Hazard Assessment. Bisphenol-A listed as known to the State of California to cause reproductive toxicity. [May 11, 2015]. http://oehha.ca.gov/proposition-65/crnr/bisphenol-listed-known-state-california-cause-reproductive-toxicity

State of California 2017b, https://www.p65warnings.ca.gov/bpalist, accessed 2/21/2017.

U.S. Environmental Protection Agency (EPA), 2010. Bisphenol A Action Plan. https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/bisphenol-bpa-action-plan

US Food and Drug Administration— 2014 (2014b) Updated safety assessment of Bisphenol A (BPA) bisphenol A for use in food contact applications. http://www.fda.gov/downloads/NewsEvents/PublicHealthFocus/UCM424266.pdf

Vandenberg LN, Chahoud I, Heindel JJ, Padmanabhan V, Paumgartten FJR, Schoenfelder G. 2010. Urinary, circulating, and tissue biomonitoring studies indicate widespread exposure to bisphenol A. Environ. Health Perspect 118:1055–1070

Yang CZ, Yaniger SI, Jordan VC, Klein DJ, Bittner GD. 2011. Most plastic products release estrogenic chemicals: a potential health problem that can be solved. Environmental Health Perspectives. 119:993. http://dx.doi.org/10.1289/ehp.1003220

Approved by Lisa de Lima, Subcommittee Chair, to transmit to NOSB, January 17, 2017