Breast Cancer Prevention Partners
Exposing The Cause Is The Cure

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Comments on the California Safer Consumer Products Program's Final Public Background Document for Ortho-Phthalates in Food Packaging
Submitted December 19, 2019
By Breast Cancer Prevention Partners

Thank you for the opportunity to comment on the Department of Toxic Substance Control's (DTSC) Safer Consumer Products work on Food Packaging, and specifically the Background Document on Ortho-Phthalates.

Breast Cancer Prevention Partners (BCPP) is a national organization that works to prevent breast cancer by eliminating our exposure to toxic chemicals and radiation linked to the disease. We translate the growing body of scientific evidence linking breast cancer and chemical exposures from the environment and consumer products into public education and advocacy campaigns that protect our health and reduce breast cancer risk.

BCPP was actively involved in the creation and implementation of the California Safer Consumer Products (SCP) Program, from working on the enabling legislation to extensive engagement on the development of the implementing regulations. We continue to support the potential of the SCP Program to make consumer products in California safer by identifying chemicals of concern and using alternatives analyses to ensure unsafe chemicals are not replaced with equally or more toxic alternatives.

We advocated for and appreciate the addition of Food Packaging to the 2018-2020 Priority Product Work Plan and look forward to working with Program staff to support continued implementation of the Program, particularly in the food packaging realm. We hope these comments will be useful in your work.

BCPP has long been concerned about the impact of exposure to various phthalates on breast cancer risk and other potential health impacts. Phthalates are endocrine disruptors and may disrupt several hormonal systems in the human body, including the estrogen and androgen systems. Evidence links several specific phthalates to breast cancer and other negative health effects. Scientific studies have shown:[1]

- A recent meta-analysis revealed that elevated urinary di(2-ethylhexyl) phthalate (DEHP) metabolite levels were associated with an increased risk for developing breast cancer. Further molecular analysis indicated that pathways involved in tumor suppression may be altered in women with higher levels of phthalates.
- Benzyl butyl phthalate (BBP) and dibutyl phthalate (DBP) have been shown to be weakly estrogenic, cause estrogen-triggered cell responses, and act in conjunction with the body's own estrogens.

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- BBP, DBP, and diisodecyl phthalate (DiBP) have been shown to bind to androgen receptors.
- BBP and DBP have been shown to cause cell proliferation, tumor formation, and malignant invasion of breast cancer cells that are low in or lack hormone receptors, indicating that there are negative health effects of phthalates beyond their direct impact on the estrogen-regulated systems.
- High levels of diethyl phthalate (DEP) have been linked to infertility in men, while high levels of DEP and DBP have been linked to infertility in women.
- Exposure to dimethyl phthalate (DMP) has been associated with early breast development, or thelarche, in girls. Early breast development has been linked to an increased risk of developing breast cancer later in life. Higher levels of monoethyl phthalate (MEP) were associated with earlier development of pubic hair in girls, another measure of puberty onset.
- BBP, DBP and bis(2-ethylhexyl) phthalate (DEHP) have been shown in laboratory studies to increase growth of human breast cancer cells and decrease the efficacy of tamoxifen, a drug commonly used to treat breast cancer.
- DBP, BBP, and DEHP have been shown to affect the androgen system ("male" hormones) and may cause physical abnormalities in male offspring of exposed mothers, such as undescended testes, reduced distance between the anus and genitals, and other effects that would indicate a problem with normal fetal development and sex differentiation.
- Phthalate exposure is also associated with diabetes, the onset and exacerbation of asthma and possibly obesity.

Given this evidence and the potential for human exposure to phthalates from food packaging and processing, we strongly support the Program's interest in this product/chemical pair. It is worth noting that the Food Safety Alliance for Packaging has issued **Food Packaging Product Stewardship Considerations** that note phthalates should not be used as plasticisers and additives in packaging materials including inks, adhesives, plastics, etc., where suitable alternatives exist.[2]

We also encourage you to include in the scope under examination not only the 'final' food packaging articles themselves, but also the materials used in the food processing and preparation-prior-to-purchase/consumption phases. Particularly for phthalates, these are also significant sources of exposure from migration into the food. See for example information below on phthalates in vinyl gloves used in food preparation which are imparting phthalates to food in restaurants, delis, cafeterias and elsewhere. Other examples of food processing sources of phthalates into food are tubing and conveyer belts.

General Comments

The FDA has approved ortho-phthalates for use as plasticizers, binders, coating agents, defoamers, gasket closures, and slimicide agents in materials that come into contact with food such as cellophane, paper and paperboard, and plastics. The FDA has approved numerous specific phthalates including butyl benzyl phthalate (BBP), diisononyl phthalate (DINP),

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dicyclohexyl phthalate (DCHP), dihexyl phthalate (DHexP), di(2-ethylhexyl) phthalate (DEHP), din-octyl phthalate (DnOP), diisodecyl phthalate (DIDP) and dibutyl phthalate (DBP), amongst others.

Specific Comments on Manufacturing

• Which OPs are currently used in food packaging and what products are they used in?

Carlos et al (2018) analyzed which plasticizers were present in domestic and international products including tubing and belts, non-alcoholic bottled beverages, bottled beer, food wraps and jarred food products[3]. They found numerous ortho-phthalates as well as several other plasticizers, including:

- DEHP, DINP and DIDP at concentrations ranging from 6 to 53%.
- Diethylhexyl adipate (DEHA), and diisononyl adipate (DINA)in food service wraps and commercial wraps
- DINP as the primary plasticizer in all five of the conveyor belt samples.
- DEHP, Acetyl Tri-n-Butyl Citrate (ATBC) and DIDP in the tubing products.
- DEHA, DEHP, DIDP or DINP, as well as other plasticizers such as 1,2-cyclohexane dicarboxylic acid diisononyl ester (DINCH) or Epoxidized soybean oil (ESBO) in the gaskets of the caps for non-alcoholic bottled beverages.
- DEHP or DEHT in bottled beers.
- DEHP (international products) or DIDP (domestic products) in jarred food products.

• What alternatives to OPs are being used as plasticizers in food packaging?

Some of the non-phthalate alternatives the FDA has approved are diethylhexyl adipate (DEHA), diethylhexyl terephthalate (DEHT), acetyl tributyl citrate (ATBC) and epoxidised soybean oil (ESBO). The results of work by Carlos et al (reference above) indicate that manufacturers seem to be switching away from phthalates as their primary plasticizer to alternate compounds such as ESBO, ATBC, DEHT, DINCH, DEHA and DINA.

Specific Comments on Market Presence

• How much food packaging containing OPs, and what types, are on the market in California and Nationally?

Phthalates can be found in the following steps phases of food preparation and packaging:

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Food packaging
Paper and paperboard with recycled content – here phthalates are present at relatively high levels, probably from their use in adhesives in corrugated cardboard and possibly some printing inks that get carried forward from the virgin material into all recycled-content paper and paperboard.

Vinyl cap gaskets used to seal metal bottle caps and metal jar lids. The phthalates are used more frequently in bottle caps.

Some adhesives, inks and coatings, but unfortunately there is little data and it is hard to identify which packaging may still carry these uses of phthalates

Potentially some metal can linings where BPA-based epoxy has been replaced with vinyl or vinyl co-polymers that may contain phthalates

Food Preparation
Some vinyl plastic disposable food service gloves found in fast food restaurants, grocery delis, school cafeterias and elsewhere may still contain phthalates, including DEHP, DINP, DIDP, and DPHP. See the Ecology Center (Michigan) *Healthy Stuff* program's report *Taking off the Toxic Gloves: An Investigation of Phthalates and Other Chemicals of Concern in Food Handling Gloves* for more information on "phthalates and other chemicals of concern" in 101 types of disposable gloves used to handle food.[4]

Food Processing
In almost every conveyor belt used in food processing plants

In many vinyl plastic tubing brands used for food processing and on some dairy farms

In some rubber inflations (teat cup liners) used on dairy farms

In other miscellaneous uses of plastics and rubber in food contact materials may contain phthalates

It is also worth noting that phthalates are also used in catalysts for polyethylene and polypropylene. Consumer Product Safety Commission report entitled *Exposure Assessment: Potential for the Presence of Phthalates in Specified Materials at Concentrations Above 0.1 Percent*[v] found that eight different plastics contained two to four phthalates from their use as manufacturing process aids.

Phthalates are also used in the manufacture of polyolefins, as it is part of the Ziegler Natta catalyst. However, phthalate levels here are lower than when used as a plasticizer.

• Who makes bottle caps and gaskets sold in California that contain OPs?

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• Do you have any specific data on the market presence of food packaging containing OPs and the supply chain?

Specific Comments on Supply Chain

- **Who manufactures and supplies the OPs or OP-containing starting materials (e.g., plastisol) to food packaging manufacturers?**
  There are a dozen or more manufacturers of phthalates in Asia including: BASF, Evonik, ExxonMobil, Polynt, Mitsubishi Chemical, UPC Group, Sari Daya Plasindo (SDP), Aekyung Petrochemical, Xiongye Chem, Kunshan Hefeng, PNK, AO Chemicals Company and 2 manufacturers in the USA: Eastman and Exxon.

Thank you for the opportunity to provide comments on the Background Document on Ortho-Phthalates. We look forward to working with the Program on this important issue and hope the information provided in these comments will assist the Program in moving forward to protect Californians from exposure to these dangerous chemicals from food packaging and processing.

[1] All references can be found at https://www.bcpp.org/resource/phthalates/.
[2] https:\www.iopp.org\files\Food Packaging Product Stewardship Considerations FSAP-IoPP v1_0.pdf
[3] Katherine S. Carlos, Lowri S. de Jager & Timothy H. Begley (2018) Investigation of the primary plasticisers present in polyvinyl chloride (PVC) products currently authorised as food contact materials, Food Additives & Contaminants: Part A, 35:6, 1214-1222, DOI: 10.1080/19440049.2018.1447695
[4] https://www.ecocenter.org/healthy-stuff/reports/vinyl-gloves-study-2019 (Accessed Dec. 2019).
[v] https://www.cpsc.gov/s3fs-public/ThePotentialforPhthalatesinSelectedPlastics.pdf (Accessed Dec. 2019).