



## ***Flexible Vinyl Alliance***

December 19<sup>th</sup>, 2019

### **Via Electronic Mail**

Safer Consumer Products Branch  
California Department of Toxic Substances Control  
P.O. Box 806  
Sacramento, California 95812-0806  
Submitted via CalSAFER Comment Portal

**Re: Comments on DTSC Work Plan Implementation: Ortho-phthalates in Food Packaging**

Dear Sir or Madam:

The Flexible Vinyl Alliance (FVA)<sup>1</sup> is pleased to submit these comments to the Safer Consumer Products Branch of the California Department of Toxic Substances Control (DTSC) regarding your proposal to evaluate food packaging containing ortho-phthalates for possible designation as Priority Products under the Safer Consumer Products Regulations (SCPR). We appreciate the opportunity to provide public comments on this process and, as a broad industry coalition, are committed to engaging with DTSC and other governmental bodies to ensure that science-based regulatory measures are adopted to promote public confidence in the safety of food packaging materials.

These comments respond to the questions presented by DTSC in their “Work Plan Implementation: Phthalates in Food Packaging” document regarding the use of ortho-phthalates in food packaging.<sup>2</sup> These comments also express our concern that DTSC is using valuable time and public resources to evaluate and regulate a series of compounds that are the subject of

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<sup>1</sup> FVA is a coalition of trade organizations, materials suppliers, compounders, formulators, molders and fabricators, who are currently concerned with regulatory and legislative attempts to debate, limit or “de-select” flexible vinyl products in commerce. FVA provides messaging and advocacy on the proven safety, economy and utility of flexible PVC, a material used in a wide range of health care, recreational, military, automotive, building, flooring, construction and packaging applications.

<sup>2</sup> See Work Plan Implementation: Phthalates in Food Packaging, October 2019, available at [https://dtsc.ca.gov/wp-content/uploads/sites/31/2019/10/Final-Public-Background-Document\\_FoPa\\_Ortho-phthalates.pdf](https://dtsc.ca.gov/wp-content/uploads/sites/31/2019/10/Final-Public-Background-Document_FoPa_Ortho-phthalates.pdf).

pending federal regulation by the U.S. Food and Drug Administration (FDA). We therefore urge DTSC to allow FDA to complete its Congressionally mandated job and not interfere in the carefully crafted system established by Congress and FDA to ensure the safety of food packaging.

### **I. Extensive Surveying of Industry Confirms that Almost All of the Authorized Uses of Ortho-phthalates in Food Packaging are Abandoned**

The members of FVA include plasticizer manufacturers, compounders, formulators, molders and fabricators of plasticized polyvinyl chloride (PVC).<sup>3</sup> FVA, through its relationships with additional trade association partners, comprehensively represents flexible vinyl business interests and addresses issues relevant to the production of an array of flexible PVC applications in a variety of consumer products. FVA conducted extensive outreach across industry to determine whether ortho-phthalates currently authorized for use by FDA in food-contact applications are still used. This included outreach to phthalate and PVC resin manufactures, convertors and finished article manufacturers, food manufacturers, as well as several different trade associations representing stakeholders in the chemical, food packaging and food manufacturing sectors. FVA confirmed through this outreach that almost all the clearances for ortho-phthalates in food packaging are not utilized by industry.

Based on this outreach, FVA formally petitioned FDA to remove the existing clearances for 26 ortho-phthalates authorized for use in food packaging on the basis that these uses are abandoned.<sup>4</sup> Recent articles from FDA scientists published in professional, peer reviewed journals also confirm these phthalates are not used in food packaging applications.<sup>5</sup> We note that many of the ortho-phthalates our members seek to formally abandon have been phased out of use for many years, as manufacturers have continually worked to refine, improve, and innovate new products. FDA is actively reviewing FVA's petition. FDA also is reviewing a separate petition submitted by a group of NGOs calling on the Agency to revoke the clearances for these 26 phthalates, as well as several others, on the basis that they are no longer safe.<sup>6</sup>

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<sup>3</sup> Ortho-phthalates are primarily used as plasticizers for PVC. *See, e.g.*, Phthalates Action Plan, U.S. Environmental Protection Agency, available at [https://www.epa.gov/sites/production/files/2015-09/documents/phthalates\\_actionplan\\_revised\\_2012-03-14.pdf](https://www.epa.gov/sites/production/files/2015-09/documents/phthalates_actionplan_revised_2012-03-14.pdf).

<sup>4</sup> A complete list of these 26 ortho-phthalates is available in the federal register notice FDA published announcing the filing of FVA's petition. *See* 83 Fed. Reg. 56750 (Nov. 14, 2018).

<sup>5</sup> Katherine S. Carlos et al, Investigation of the Primary Plasticizers Present in Polyvinyl Chloride (PVC) Products Currently Authorized as Food Contact Materials, Food Additives & Contaminants (2018).

<sup>6</sup> *See* 81 Fed. Reg. 31877 (May 20, 2016). The NGO's FAP maintains that the current exposures to the phthalates that are the subject of the FAP exceed safe levels, and therefore the

FDA is therefore poised to act to revoke the clearances for these 26 ortho-phthalates when used in food packaging applications. Any state efforts to regulate these phthalates out of commerce are therefore unnecessary and redundant, as this issue is already dealt with at the federal level by the scientific experts on food packaging at FDA. In this regard, we note that FDA notified FVA in May of 2019 that it had completed its review of the abandonment petition and is drafting a final response to the petition in the Federal Register.

**II. FDA is Currently Evaluating the Safety of the Four Ortho-phthalates that are Still Used in Food Packaging**

FVA’s survey of industry confirmed only four ortho-phthalates are still used as additives in food packaging applications: Diisononyl Phthalate (DINP), Diisodecyl Phthalate (DIDP), Di(2-ethylhexyl) Phthalate (DEHP) and dicyclohexyl phthalate (DCHP). Table I summarizes the current uses for these substances in food packaging.

<b>Table I: Current Food Packaging Applications for DINP, DIDP, DEHP and DCHP</b>	
<b>Ortho-phthalate</b>	<b>Current Food Packaging Applications</b>
DINP	Liners in beverage closures and dry food film wrap
DIDP	Beverage cap liners and seals for metal closures
DEHP	Beverage cap liners and seals for metal closures
DCHP	Component of adhesive used to affix labels to the exterior of food-contact polypropylene containers

The relevant food packaging clearances and applications for DINP, DIDP and DEHP limit their use to non-fatty, aqueous food. Available data shows these substances are largely insoluble in water. DCHP is only used as a component of adhesives that affix labels to the exterior of polypropylene containers that contact food.<sup>7</sup> The exposures associated with these applications are therefore very, very small.

existing food-contact clearances for phthalates under FDA’s food additive regulations should be removed.

<sup>7</sup> Based on the intended conditions of use for DCHP, the relevant regulation permitting the use of DCHP in this application is 21 C.F.R. § 175.105 (“Adhesives”). Section 175.105 requires that adhesives used in food packaging must be (a) separated from food by a functional barrier, (b) used such that the quantity of adhesive contacting dry food does not exceed the limits of Good Manufacturing Practices (GMP), or (c) for aqueous and fatty foods, used so that the

Although adverse effects were observed in some phthalate feeding studies in rats and mice, FDA and others also have noted that these effects were observed at quite high doses and may not even be relevant to humans.<sup>8</sup> Additionally, FDA scientists recently noted “[t]here have been no studies to date which show any connection between human dietary exposures to phthalates and adverse health effects.”<sup>9</sup> Regardless, FVA already provided detailed information to FDA about the use applications for these four materials and, as discussed above, FDA is currently evaluating their safety and is expected to reach a decision soon. In the meantime, the European Food Safety Authority (EFSA) Panel on Food Contact Materials, Enzymes and Processing Aids (CEP Panel) recently published an opinion on phthalates where it concluded that exposures to phthalates associated with their use in food packaging are far below safe levels.<sup>10</sup> DTSC’s action to scrutinize and possibly regulate these four ortho-phthalates is therefore an unnecessary and redundant activity.

### **III. FDA Regulates the Safety of Our Nation’s Food Packaging through a Carefully Crafted and Comprehensive Regulatory Scheme Established by the U.S. Congress**

In 1958, Congress amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to establish a single premarket clearance procedure for food additives and food packaging materials. This premarket clearance process requires the Agency to review the safety of a material before it is placed on the market, unless a preexisting regulatory clearance or exemption applies. FDA experts are currently reevaluating the safety of the few phthalates that are still used in food packaging applications based on the current scientific evidence available. FDA has developed a staff of excellent scientists to evaluate these materials, and these officials are some of the top experts in the world.

Permitting states to scrutinize and ban products that FDA has already determined to be safe thwarts the single market for the nation’s food supply that Congress and FDA have, quite explicitly, intended to create. State scrutiny and prohibitions for food packaging materials create consumer confusion and erode public confidence in FDA and in the safety of the nation’s food

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quantity of adhesive contacting food does not exceed the trace amounts at the seams and edges that may occur within the limits of GMP. Thus, for an adhesive formulation to be used in compliance with Section 175.105, it must be used under conditions that prevent the adhesive from becoming a component of food in more than insignificant, *de minimis*, amounts. DCHP is not used in direct contact with food and any exposures associated with its use in this application are therefore *de minimis*.

<sup>8</sup> Carlos et al.

<sup>9</sup> *Id.*

<sup>10</sup> *Update of the risk assessment of di-butylphthalate (DBP), butyl-benzyl-phthalate (BBP), bis(2-ethylhexyl)phthalate (DEHP), di-isononylphthalate (DINP) and diisodecylphthalate (DIDP) for use in food contact materials*, EFSA Journal, September 18, 2019 available at [http://www.efsa.europa.eu/sites/default/files/scientific\\_output/efs2\\_5838\\_Rev4.pdf](http://www.efsa.europa.eu/sites/default/files/scientific_output/efs2_5838_Rev4.pdf).

supply. The costs of food and food packaging materials simultaneously increase with the establishment of varying state initiatives that create legal uncertainty and force label changes. The lack of a single federal framework for regulating food and food packaging materials also increases food waste.

This comprehensive federal scheme also preempts any state laws or regulations that seek to regulate substances that have been deemed safe for use by FDA in food additives and packaging materials. Specifically, under the U.S. Constitution’s Supremacy Clause, where a state ban “stands as an obstacle to the accomplishment and execution of the full purposes and objectives” of a federal statute, the ban conflicts with federal law and cannot be enforced.<sup>11</sup> Further action by DTSC with respect to ortho-phthalates used in food packaging applications would present an obstacle to a federal scheme that permits the safe use of certain ortho-phthalates in food packaging.

#### **IV. DTSC is Required to Avoid Duplicative Regulatory Efforts and to Minimize Costs to the State**

California’s Green Chemistry law, passed in 2008, provides that DTSC shall “reference and use, to the maximum extent feasible, available information from other nations, governments and authoritative bodies that have undertaken similar chemical prioritization processes, so as to leverage the work and costs already incurred by those entities and to minimize costs and maximize benefits for the state’s economy.”<sup>12</sup> The law elsewhere states that it “does not authorize [DTSC] to supersede the regulatory authority of any other department or agency”, nor shall DTSC “duplicate or adopt conflicting regulations for product categories already regulated or subject to pending regulation...”<sup>13</sup>

As discussed above, food packaging materials are regulated at the federal level pursuant to a carefully crafted scheme adopted by Congress that is implemented and administered by FDA. Moreover, FDA is poised to act on multiple petitions relating to the current clearances for ortho-phthalates that authorize their use in food packaging applications. Any action by DTSC to further scrutinize these substances is therefore not only unnecessary and redundant, but also violative of California’s own statute governing the SCPR.

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<sup>11</sup> *Geier v. Am Honda Motor Co., Inc.*, 529 U.S. 861, 873 (2000); *see also Zogenix, Inc. v. Patrick*, 2014 U.S. LEXIS 51840 (D. Mass. 2014) (finding Massachusetts’ ban on an opioid unconstitutional because the drug had been approved by FDA as safe and effective).

<sup>12</sup> Cal Health & Safety Code § 25252(b)(2).

<sup>13</sup> Cal Health & Safety Code § 25257.1(b)-(c).

Should you have any questions related to these comments, please do not hesitate to contact us. We appreciate the opportunity to provide this input.

Sincerely,

A handwritten signature in black ink, appearing to read "Kevin D. Ott". The signature is fluid and cursive, with a distinct loop at the end.

Flexible Vinyl Alliance (FVA)  
1400 Crystal Drive  
Suite 631  
Arlington, VA 22202  
571-348-5100  
[www.flexvinylalliance.com](http://www.flexvinylalliance.com)

Executive Director:  
Kevin D. Ott  
Principal  
Ott Consulting Group LLC