



Flexible Vinyl Alliance

To: United State Food & Drug Administration

From Kevin Ott, Executive Director, Flexible Vinyl Alliance

Re: Comments to FDA Docket 2022-N-0571

Date: December 22, 2022

Introduction

On behalf of the Flexible Vinyl Alliance, it is our pleasure to provide the U.S. Food & Drug Administration additional support and commentary to assist with ongoing risk evaluations of certain ortho-phthalates as detailed in the FDA's Request for Information (RFI) of May 20, 2022.

As you are aware, FVA was the petitioner of record on 8B4820, accepted by FDA on May 19, 2022.

As FVA explained in its petition, there remain **just four** phthalates that "remain relevant in food contact applications." These include: di(2-ethylhexyl) phthalate (DEHP, CAS 117-81-7), diisononyl phthalate (DINP, CAS 28553-12-0), dicyclohexyl phthalate (DCHP, CAS 84-61-7), and diisodecyl phthalate (DIDP, CAS 26761-40-0).

We fully concur with the decision made at the time by FDA and note that it is aligned with existing conclusions reached by other similar food safety agencies around the world, including the EU,¹ Australia,² UK,³ and Ireland⁴. All these agencies agree, exposures to phthalates in food are low and pose no public health concerns in the diet. Similar to U.S. FDA, other countries continue to maintain authorizations for the use of some of these phthalates in food contact applications, including DEHP, DINP, and DIDP.⁵ We will now speak to what may or may not have changed in terms of exposure and use of these phthalates in the United States since May of 2022, as the FDA once again seeks to initiate enhanced risk assessments around DIDP, DINP, DEHP and DCHP.

Flexible Vinyl Alliance (FVA)

FVA is a coalition of trade organizations, materials suppliers, compounders, formulators, molders, and fabricators/converters who are currently concerned with regulatory and legislative attempts to limit or "de-select" flexible vinyl products in commerce. The FVA provides messaging and advocacy on the

¹ [Update of the risk assessment of di-butylphthalate \(DBP\), butyl-benzyl-phthalate \(BBP\), bis\(2-ethylhexyl\)phthalate \(DEHP\), di-isononylphthalate \(DINP\) and di-isodecylphthalate \(DIDP\) for use in food contact materials | EFSA \(europa.eu\)](#)

² [Survey of Plasticisers in Australian Foods \(foodstandards.gov.au\)](#)

³ [Microsoft Word - phthalates statement 04-11.docx \(food.gov.uk\)](#)

⁴ [FSAI publishes results of total diet study](#)

⁵ See COMMISSION REGULATION (EU) No 10/2011

proven safety, economy, and utility of flexible PVC, including the relevant plasticizers used to impart function and performance to hundreds of safe and sustainable products. Flexible PVC is a critical and widely used plastic incorporated in a wide range of health care, recreational, military, automotive, building and construction, and packaging applications.

Per FDA's website, and for the purposes of clarity: "*Ortho*-phthalates, often referred to as 'phthalates,' are chemicals used in plastic products (most commonly in the specific type of plastic named polyvinyl chloride, also known as PVC or vinyl) to make the material soft and less brittle. This function in the manufacturing of plastics is often referred to as a "plasticizer." Some phthalates may be used in food packaging or other minor food contact uses such as components of adhesives, lubricants, and sealants."

[Looking Forward from FDA's May 19 Decision on 8B4820](#)

The decision by FDA on May 19, 2022, viz. 8B4820 was science and data driven, and the correct one: <https://www.federalregister.gov/documents/2022/05/20/2022-10531/indirect-food-additives-adhesives-and-components-of-coatings-paper-and-paperboard-components>

Supplemental to that decision was a Request for Information (RFI) of May 20, 2022, <https://www.federalregister.gov/documents/2022/09/27/2022-20832/ortho-phthalates-for-food-contact-use-reopening-of-comment-period-request-for-information>, with specific asks that seek to ascertain, confirm, or amend the safety declaration(s) around the retention of authorization for DIDP, DINP, DEHP, and DCHP – common ortho-phthalates used widely in commerce for more than 50 years, but minimally, today, in food contact.

In responding to Request for Information (Docket No. FDA-2022-N-0571) in a timely manner, we emphasize, primarily via legacy information provided to FDA during the 4-year process leading to the May 19 decision, that **ortho-phthalates that remain authorized for food contact are safe.**

As stated, the 8B420 Petition process took four years. The results were clear. Now, the accompanying RFI seeks to clarify and re-visit "relevant information to support our (FDA) review of the current use levels and safe use of these ortho-phthalates in food contact applications." FDA states that (it) "is generally aware of updated toxicological and use information on phthalates that is publicly available. Nevertheless, stakeholders may have access to information that is not always made public."

While we applaud FDA's mission to provide for safety in food products, it remains relevant on this matter that **the voluminous information FVA provided during the four-year process around 8B420 remains relevant, valid, current, comprehensive, and up to date.**

Recall during that four-year data-intensive process FVA responded to all FDA inquiries, and provided all information available, including deep technical insights on usages, to assist FDA in making an informed decision on both the ortho-phthalates de-authorized for lack of use, as well as the four that now continue to be authorized.

FDA will also recall that along with our Industry Petition (8B4820), FVA submitted extensive survey data on non-use of the abandoned phthalates as well as a detailed Food Additive Master File (FMF) which was subsequently released per FDA's letter to counsel of March 7, 2022, re: "*Pre-Disclosure Notification for Food Master File (FMF) No. 954.*" **In the FMF, we outlined industry's view on the existing food-**

contact applications for the four relevant phthalates (DEHP, DINP, DCHP and DIDP). To the best of our knowledge, it is our current view that this data is also, in essence, still the case.

Now, given the considerable scope of the 2022 RFI, it requires (again) the collection of data and other related information from a variety of stakeholders to address current uses, dietary exposures, and related safety issues of the identified (4) ortho-phthalates.

However, almost all data relevant to food packaging is already public information as supported by the following informational links (as well as the FMF reference above) per *Food Additive & Contaminants* Volume 35, 2018 and Volume 38, 2021:

<https://www.tandfonline.com/doi/abs/10.1080/19440049.2018.1447695?journalCode=tfac20>

<https://www.tandfonline.com/doi/abs/10.1080/19440049.2020.1859623?journalCode=tfac20>

In our estimation, only limited “new” supplemental data may be available. But we do anticipate, if available, these data will be provided to FDA’s docket by individual FVA members and/or other stakeholders, where applicable. FVA has reached out to these stakeholders and encouraged them to contribute to the RFI docket per requests via multiple communication methods, including email, written surveys, in-person industry presentations and phone -- by the deadline of December 27, 2022.

CONCLUSIONS

As an industry, we are confident that further data assemblage, while limited, along with exposure assessments, such as contained in the original FVA-submitted FMF, will reinforce that these plasticizers (4), while minimally used in food contact **remain safe** for their intended use when deployed for food contact and food packaging.

In closing we appreciate the thoroughness and scientific rigor with which you reached the conclusion on Petition 8B420. We fully concur with FDA’s decision of May 19.

Sincerely,

Kevin D. Ott

Kevin D. Ott
Executive Director
Flexible Vinyl Alliance
a SOCMA Affiliate
1400 Crystal Drive
Suite 630
Arlington, VA 22202