Congress of the United States

Washington, DC 20515

May 19, 2023

Dr. Robert Califf
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Dr. Califf,

We write again today[1] to urge the Food and Drug Administration (FDA) to act expeditiously to protect the public from the health risks posed by ortho-phthalates (also known as phthalates) in food and food packaging. As you are aware, phthalates are a family of toxic chemicals that can cause reproductive and developmental harm. Currently, phthalates are approved for food packaging and processing equipment.[2] Specifically, we request the FDA hold a public evidentiary hearing on pending objections[3] to the FDA's denial[4] of a 2016 food additive petition[5] which urged the withdrawal of approval of all uses of phthalates as food additives. This decision was flawed, and we are deeply concerned about the denial which was made *without deciding whether the remaining approved uses of phthalates in food and food packaging are safe*.

That being said, we are pleased that you have acknowledged that chemical safety, including in food and food packaging, is a "really, really important area for the future – for humankind, really – and where science is evolving rapidly."[6] We urge the FDA to hold a public evidentiary hearing on the following specific concerns related to phthalates and the food additive petition:

- **The failure to evaluate the safety of phthalates as authorized food additives, prior to denying the above mentioned petition.** The FDA is required by law and regulation[7] to evaluate the safety of food additives and to revoke their approval when the evidence raises significant questions about their safety. The FDA cannot conclude with reasonable certainty that phthalates' continued use in food will not cause

[1] As you know, in June 2021 Members of Congress (including some of the signatories of this letter) wrote to FDA calling for a ban on phthalates in food contact materials and cosmetics. Specifically, that letter pointed to evidence linking phthalate exposure with neurodevelopmental and reproductive developmental impairments.
[2] See https://www.fda.gov/food/food-ingredients-packaging/phthalates-food-packaging-and-food-contact-applications.
[3] See EDF et al. Objections and Request for Evidentiary Public Hearing Regarding FDA's Denial of Phthalates Food Additive Petition (FAP 6B4815), Docket No. FDA-2016-F-1253, at https://www.regulations.gov/comment/FDA-2016-F-1253-0462.
[4] See https://www.regulations.gov/document/FDA-2016-F-1253-0440.
[5] See https://www.regulations.gov/document/FDA-2016-F-1253-0002. The food additive petition requested that the agency strike from its existing regulations its approvals of 28 ortho-phthalates as food additives in food contact articles; and prohibit the use of eight ortho-phthalates as food contact substances that the Consumer Products Safety Commission's Chronic Health Advisory Panel on Phthalates concluded are unsafe or the evidence indicates developmental health effects are likely.
[6] Dr. Califf interview with Helena Bottemiller Evich for Food Fix. https://foodfix.co/how-fda-plans-to-fix-its-foods-side/. January 31, 2023
[7] *See* 21 U.S.C. § 348(f)(1) (directing that FDA "*shall*" hold, "as promptly as possible," "[a] public hearing for the purpose of receiving evidence relevant and material to the issues raised by . . . objections" to an order denying a food additive petition if those objections are timely, "specify with particularity the provisions of the order deemed objectionable, stat[e] reasonable grounds therefor, and request a public hearing upon such objections") (emphasis added); 21 C.F.R. §§ 10.20, 12.22.

harm to human health after considering, as required, all related chemicals in the diet.[8] Failing to evaluate the safety of phthalates is an abdication of the FDA's "continuing obligation to oversee the safety of the food supply"[9] by assessing "whether there continues to be reasonable certainty of no harm from the use of"[10] food additives that remain approved.

- **The failure to address new toxicity information[11] that raises significant questions about the safety of phthalates as approved food additives**. These substances are associated with reproductive and developmental toxicity, endocrine disruption, immune toxicity, and epigenetic alterations.[12] The denial of the petition fails to acknowledge, let alone analyze, the dozens of peer-reviewed studies that underscore the toxicity of the phthalates that remain approved for food contact use.

While we understand the FDA sought public comment on this topic in mid-2022, a public hearing is required by law given the material factual issues. We call on the FDA to hold such a hearing to protect public health through the proper decision-making process. The FDA must move quickly to honor its mission and duty of making safety determinations based on evidence and acting accordingly to protect public health.

Sincerely,

Katie Porter
Member of Congress

Steve Cohen
Member of Congress

[8] See 21 U.S.C. 348(c)(5). (5)In determining, for the purposes of this section, whether a proposed use of a food additive is safe, the Secretary shall consider among other relevant factors—(A)the probable consumption of the additive and of any substance formed in or on food because of the use of the additive; (B)the cumulative effect of such additive in the diet of man or animals, taking into account any chemically or pharmacologically related substance or substances in such diet; and (C)safety factors which in the opinion of experts qualified by scientific training and experience to evaluate the safety of food additives are generally recognized as appropriate for the use of animal experimentation data. See also https://www.regulations.gov/comment/FDA-2016-F-1253-0462 for objections filed requesting a public hearing.

[9] 21 CFR 172.

[10] Id.

[11] The science from the past thirty years undermines the conclusion that the approved uses of phthalates in food contact substances are safe. Phthalates are known to cause reproductive and developmental harm, as demonstrated by a large body of studies, including a July 2022 Centers for Disease Control and Prevention and National Institute for Environmental Health Sciences study of pregnant people. That study found that "higher urinary metabolite concentrations for several prevalent phthalates were associated with greater odds of delivering preterm, and hypothetical interventions to reduce phthalate exposure levels were associated with fewer preterm births." Welch BM, Keil AP, Buckley JP, et al. Associations Between Prenatal Urinary Biomarkers of Phthalate Exposure and Preterm Birth: A Pooled Study of 16 US Cohorts. *JAMA Pediatr.* Published online July 11, 2022. See doi:10.1001/jamapediatrics.2022.2252. https://jamanetwork.com/journals/jamapediatrics/article-abstract. The study concluded that "phthalate exposure during pregnancy may be a preventable risk factor for preterm delivery." EPA scientists have also shown that when combined, phthalates and pesticides that affect the development of the male reproductive system "acted cumulatively to produce adverse effects at doses below which any individual chemical had been shown to produce an effect alone." Conley, JM et al. A mixture of 15 phthalates and pesticides below individual chemical no observed adverse effect levels (NOAELs) produces reproductive tract malformations in the male rat. https://www.sciencedirect.com/science/article/pii/S0160412021002403?via%3Dihub.

[12] See https://downloads.regulations.gov/FDA-2016-F-1253-0462/attachment_1.pdf.

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