UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ENVIRONMENTAL DEFENSE FUND
257 Park Avenue South
New York, NY 10010;

LEARNING DISABILITIES
ASSOCIATION OF AMERICA
4068 Mt. Royal Blvd., Suite 224B
Allison Park, PA 15101;

CENTER FOR FOOD SAFETY
660 Pennsylvania Avenue SE, #402
Washington, DC 20003;

CENTER FOR ENVIRONMENTAL HEALTH
2201 Broadway, Suite 508
Oakland, CA 94612;

CENTER FOR SCIENCE IN THE PUBLIC INTEREST
1250 L Street NW, Suite 500
Washington, DC 20005;

BREAST CANCER PREVENTION PARTNERS
1388 Sutter Street, Suite 400
San Francisco, CA 94109;

DEFEND OUR HEALTH
565 Congress Street, Suite 204
Portland, ME 04101; and

ALASKA COMMUNITY ACTION ON TOXICS
1225 E International Airport Road, Suite 220
Anchorage, AK 99518;

Plaintiffs,

v.

U.S. FOOD AND DRUG ADMINISTRATION and DR. ROBERT CALIFF, in his official capacity as Commissioner of the U.S. Food and Drug Administration,

Defendants.

Case No. 1:21-cv-03190 (RDM)

AMENDED COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

INTRODUCTION

1. Plaintiffs Environmental Defense Fund, Learning Disabilities Association of America, Center for Food Safety, Center for Environmental Health, Center for Science in the Public Interest, Breast Cancer Prevention Partners, Defend Our Health, and Alaska Community Action on Toxics (collectively, "Plaintiffs") bring this civil action against the U.S. Food and Drug Administration ("FDA") and Dr. Robert Califf, Commissioner of the FDA (collectively, "Defendants" or "FDA").

2. Plaintiffs seek relief from FDA's unlawful denials of a 2016 citizen petition submitted by six of the Plaintiffs and other allied groups (collectively, the "Food Safety Groups") and a subsequent petition for reconsideration of that denial. The citizen petition asks FDA to restrict the use of ortho-phthalate esters (a class of chemicals referred to here as "phthalates") in food packaging and food processing materials based on evidence linking phthalates to a range of harmful health effects. Specifically, the petition asks FDA to (1) promulgate new regulations prohibiting food contact uses of eight phthalates that the Consumer Product Safety Commission's expert panel on phthalates determined are unsafe or likely to cause developmental harm, and (2) remove five phthalates from FDA's list of "prior-sanctioned substances," which consists of substances approved by FDA for use in food or food packaging before September 1958.

3. A robust body of scientific evidence links human exposure to phthalates with serious harm to human health, including birth defects, infertility, miscarriage, and irreversible damage to the developing brain. Indeed, evidence of phthalates' harmful effects on human health led Congress and the Consumer Product Safety Commission to ban eight of the phthalates addressed by the Food Safety Groups' petition from use in toys and childcare articles. Yet these

chemicals remain FDA-approved for use in food packaging and processing materials from which they can leach into food and drinks.

4. Ingestion of food and drinks contaminated by phthalates is the primary way that most people in the United States—including children—are exposed to most phthalates. Today, nearly every child and adult in the United States has measurable levels of phthalates in their body.

5. Despite its statutory mandate to "protect the public health by ensuring that . . . foods are safe," 21 U.S.C. § 393(b)(2)(A), FDA unlawfully denied the Food Safety Groups' 2016 citizen petition to eliminate toxic phthalates from food and Plaintiffs' subsequent petition for reconsideration of that denial. As a result, Plaintiffs' members and supporters and their children continue to suffer exposure to these dangerous chemicals in their food. To remedy FDA's unlawful action on the 2016 citizen petition and related petition for reconsideration, Plaintiffs seek an order from this Court declaring unlawful FDA's denials of the citizen petition and related reconsideration petition, vacating those unlawful decisions, and remanding this matter to the agency.

JURISDICTION AND VENUE

6. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331 (federal question); the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 702, 706(2); and the Federal Food, Drug, and Cosmetic Act (the "Food Act"), 21 U.S.C. § 301 *et seq.* *See In re Nat. Res. Def. Council*, 645 F.3d 400, 402, 406–07 (D.C. Cir. 2011) (explaining that FDA's denial of a citizen petition is reviewable in district court). The relief requested is authorized by 5 U.S.C. § 706(2) and 28 U.S.C. §§ 2201–2202.

7. Venue is proper in this Court under 28 U.S.C. § 1391(e)(1)(A)–(C) because the federal defendants reside in this judicial district, a substantial part of the events or omissions giving rise to Plaintiffs' claims occurred in this judicial district, and Plaintiff Center for Science in the Public Interest has its principal place of business in this judicial district and no real property is involved in this action.

PARTIES

8. Plaintiffs are non-profit organizations with longstanding commitments to protecting people from dangerous exposure to phthalates in food, in household and personal care products, and from industrial facilities. On behalf of their members, board members, volunteers, staff, and other supporters, Plaintiffs advocate for health-protective changes to federal and state laws governing phthalates in food and other products, press companies to eliminate phthalates from their supply chains, and educate their members and supporters about the health risks from phthalate exposure and ways to reduce that exposure. Plaintiffs' members and supporters support and participate in Plaintiffs' advocacy to reduce phthalate exposure from food and other sources through financial donations, submitting comments to federal and state regulators, providing testimony to legislative bodies, informing the Plaintiff organizations of their concerns and priorities for this body of advocacy, and other means. As described below, because of FDA's denials of the 2016 citizen petition and related petition for reconsideration, Plaintiffs' members and supporters and their children have experienced and continue to experience dietary exposure to FDA-approved phthalates that endangers their health.

9. Plaintiff Environmental Defense Fund ("EDF") is a non-profit organization headquartered in New York with a staff of more than 750 scientists, economists, policy experts, and other professionals in offices around the world. On behalf of more than 415,000 members

from across the United States, EDF works to protect public health by reducing exposure to toxic chemicals in food, drinking water, and household products. EDF is deeply engaged in advocacy to ensure that food is free from harmful chemicals and contaminants such as heavy metals, perchlorate, per- and polyfluorinated alkyl substances, and phthalates. A key component of this advocacy involves EDF's submission of rulemaking petitions to FDA that seek health-protective changes to the federal rules governing food additives. For example, in 2018, EDF and its partners successfully petitioned FDA to remove several carcinogenic flavor additives from the market. In 2014, EDF and its partners successfully petitioned FDA to ban uses of dangerous perfluorinated alkyl substances in food contact materials. EDF serves its members and the broader public by providing scientific and legal expertise that is necessary to participate effectively in the petitions process. EDF was a party to the 2016 citizen petition at issue in this case as well as a closely related food additive petition that together ask FDA to revoke all of FDA's existing authorizations for uses of phthalates in food packaging and processing materials.

10. Plaintiff Learning Disabilities Association of America ("LDA") is a non-profit organization headquartered in Pittsburgh, Pennsylvania, with state and local chapters throughout the country. LDA has approximately 2,000 dues-paying members nationwide and engages approximately 43,000 supporters through its email communications. LDA's mission is to create opportunities for success for all individuals affected by learning disabilities through support, education, and advocacy. A core component of LDA's work is to promote research into the causes of learning disabilities and other neurological disorders and advocate for policies that will reduce the number of individuals affected by learning disabilities. LDA has established a Healthy Children Project to advance these objectives by raising awareness about the link between toxic chemical exposure and harm to brain development and by advancing policies that

will reduce these exposures, especially among pregnant people and young children. As part of this work, LDA was a party to the 2016 citizen petition and related food additive petition asking FDA to prohibit the use of phthalates in food packaging and processing materials.

11. Plaintiff Center for Food Safety ("CFS") is a tax-exempt, 501(c)(3) non-profit membership organization with offices in Portland, Oregon; San Francisco, California; and Washington, D.C.; as well as staff located remotely across the country. CFS was established in 1997 to protect its staff and members' right to safe food and the environment. CFS represents more than one million farmer and consumer members from every state across the country. CFS's mission is to protect human health and the environment from the harmful impacts of industrial food production. Through public education, science-based advocacy, grassroots outreach, and groundbreaking legal action, CFS works to curb the use of harmful food production technologies, including unsafe food additives, and to promote safe and sustainable alternatives. To achieve its mission, CFS provides oversight of governmental activities surrounding the safety of our food supply. CFS develops and disseminates a wide variety of educational and informational materials regarding the potential health impacts of food production technologies to CFS members and other diverse audiences to educate consumers about potentially unsafe food products and facilitate their participation in regulatory decision-making processes regarding food policy and laws. CFS also works to protect its members and consumers by submitting rulemaking petitions to FDA to improve federal food additive regulations. CFS was a party to the 2016 citizen petition at issue in this case and the related food additive petition. In addition, CFS submitted a 2014 food additive petition seeking to revoke FDA's approval of the hormone-disrupting chemical perchlorate as a food additive, a 2014 food additive petition that led FDA to ban the use of unsafe perfluorinated alkyl substances in food

contact materials, and a 2018 food additive petition that led FDA to ban six carcinogenic flavor additives.

12. Plaintiff Center for Environmental Health ("CEH") is a non-profit organization headquartered in Oakland, California. CEH's work is guided by its twelve board members and its network of more than 50,000 supporters across the United States. For more than twenty years, CEH has helped lead the growing, nationwide effort to protect people from toxic chemicals that cause cancer, adverse reproductive effects, learning disabilities, and many other health problems. In particular, CEH works to protect children from toxic chemicals, as their behaviors and physical characteristics make them more vulnerable to harm from chemical exposure than adults. CEH uses a range of strategies to achieve this goal—from public education to legal action. For instance, CEH works with state and federal policymakers to develop laws and regulations that support safer chemicals and consumer products. CEH also fights to ensure that governments allocate sufficient resources to implement those laws and regulations in a way that protects families from toxic chemicals. CEH conducts product testing to identify sources of toxic chemicals in food packaging and other products and advises companies in the development of business practices that do not harm people or the environment. CEH also protects people from immediate toxic threats by enforcing existing laws. CEH devotes substantial resources to addressing the health threats from exposure to hormone-disrupting chemicals in food, food packaging, and other consumer products. As part of this body of work, CEH joined the 2016 citizen petition giving rise to this lawsuit and the related food additive petition.

13. Plaintiff Center for Science in the Public Interest ("CSPI") is a non-profit consumer education and advocacy organization headquartered in Washington, D.C., that has

worked since 1971 to improve the public's health through better nutrition and safer food. CSPI provides nutrition and food safety information directly to consumers, and has long advocated for legislation, regulation, and judicial rulings to ensure that foods are safe and clearly labeled. CSPI is supported by foundations and its approximately 280,000 members, including individual donors and individuals who receive its health and nutrition newsletter, *Nutrition Action*, which is sometimes received as a CSPI membership benefit. Through its newsletter and online communications, CSPI engages with its members, who provide the majority of financial support for the organization and help shape its priorities. CSPI engages in extensive public education and advocacy related to toxic food additives. This body of work includes developing and disseminating information to CSPI's members regarding the health risks posed by dietary exposure to phthalates and other chemicals and advocacy to FDA to strengthen legal protections for human health. CSPI is a party to the 2016 citizen petition giving rise to this case and the related food additive petition.

14. Plaintiff Breast Cancer Prevention Partners ("BCPP") is a non-profit organization headquartered in San Francisco, California. BCPP works at the intersection of breast cancer prevention and environmental health. For more than twenty-five years, BCPP has engaged in science-based policy and advocacy work with the goal of preventing breast cancer by eliminating exposure to toxic chemicals and radiation. To advance these goals, BCPP educates its supporters and the broader public about toxic chemicals that have been linked to cancer—many of which are found in food and consumer products—and steps people can take to reduce their exposure. BCPP also advocates to companies to remove cancer-causing chemicals from their products and to policymakers at the federal and state levels for policy changes that will protect people from exposure to cancer-causing chemicals. BCPP's work is driven and shaped by the organization's

sixteen independent board members and 20,000 supporters from across the country, who engage directly with the organization by seeking advice about ways to reduce their exposure to toxic chemicals, by raising concerns about specific chemicals or products for BCPP to investigate, and by engaging in BCPP's advocacy campaigns. BCPP has engaged in extensive public education and advocacy to eliminate toxic chemicals, including phthalates, from food packaging and food processing equipment. As part of that work, BCPP (then called Breast Cancer Fund) joined the 2016 citizen petition at issue in this case and the related food additive petition.

15. Plaintiff Defend Our Health is a non-profit organization headquartered in Portland, Maine, that is dedicated to creating a world where all people have equal access to safe food and drinking water, healthy homes, and products that are toxic-free. Defend Our Health engages in policy advocacy at the state and federal levels and pursues market-based strategies to encourage companies to identify toxic chemicals such as phthalates in their supply chains and switch to safer alternatives. In addition, Defend Our Health has conducted and commissioned product testing and other research to identify toxic chemicals, including phthalates, in food and other products. Defend Our Health uses the results of this research to inform its advocacy and to educate its supporters and the broader public about toxic chemical threats, strategies to reduce exposure, and ways to engage in regulatory and other policy processes to advocate for changes in the law that will better protect human health. Through its Toxic-Free Food campaign, Defend Our Health has conducted extensive research, public education, regulatory advocacy, and direct advocacy to companies regarding the urgent need to eliminate uses of phthalates in food packaging and processing materials. Defend Our Health empowers its supporters to participate in regulatory and legislative advocacy and consumer campaigns.

16. Plaintiff Alaska Community Action on Toxics ("ACAT") is a women-led non-profit advocacy organization headquartered in Anchorage, Alaska. Driven by a core belief in environmental justice, ACAT empowers communities across Alaska to eliminate exposure to toxic chemicals through collaborative research, shared science, education, organizing, and advocacy. ACAT engages in policy advocacy at the federal and state levels to reduce exposure to toxic chemicals in the natural and built environments, products, and food. ACAT advocates to address the particular concerns of, and threats to, its supporters and partner communities in Alaska—including Arctic Indigenous Peoples who rely on traditional subsistence foods that are threatened by toxic chemical contamination as well as rural communities with constrained food choices and a heavy dependence on processed and packaged foods. ACAT engages in community organizing and leadership development in communities across Alaska, from low-income urban communities in Anchorage to rural villages. ACAT's work is steered by a board of directors consisting primarily of Arctic Indigenous women and is informed by the priorities and requests for support the organization receives from its grassroots partners and supporters.

17. Each of the Plaintiff organizations joined the 2022 petition for reconsideration of FDA's denial of the 2016 citizen petition. In addition, each of the Plaintiff organizations is a party to administrative objections that seek reconsideration of FDA's decision denying a related food additive petition to restrict the use of phthalates in food contact materials, described *infra.*

18. Each of the Plaintiff organizations has members, board members, staff, and/or other supporters who have been harmed by FDA's denials of the 2016 citizen petition and related reconsideration petition and will continue to be harmed so long as FDA refuses to restrict the use of the phthalates addressed in the citizen petition.

19. Plaintiffs' members and supporters and their children regularly consume a variety of food products that are packaged or processed with materials containing FDA-approved phthalates, and in which phthalate contamination has been detected, including milk and other dairy products, meat, seafood, spices, cooking oils, baked goods, grains, and an array of packaged and processed foods.

20. For example, CSPI member Jean Bissell and her husband regularly consume several gallons of milk per week. ACAT supporter Margaret Yellow Wolf Tarrant's adolescent children drink milk with their cereal every day. LDA member Alexandra Moulton's young children eat yogurt every day, and they eat frozen chicken nuggets and boxed macaroni and cheese several times per week. EDF member Paul Ames and his wife regularly eat takeout meals from their local deli and local restaurants. CEH supporter Rachel Doughty and her children regularly eat yogurt and cheese.

21. While Plaintiffs' members are aware of, and deeply concerned about, the tendency for phthalates to leach out of food packaging and processing materials into these foods, they are unable to avoid this exposure so long as phthalates are FDA-approved for use in food packaging and processing materials. Because the presence of phthalates in these and other foods is not disclosed on food labels or restaurant menus, Plaintiffs' members are left to guess based on incomplete information which foods may contain phthalates and the extent of phthalate contamination in various foods.

22. In addition, many of Plaintiffs' members and supporters have significant constraints on their food choices that undermine their ability to reduce their exposure and their children's exposure to phthalates in their diet.

23. For example, many of ACAT's board members, staff, and supporters live in rural villages in Alaska where fresh produce is scarce and often prohibitively expensive, leading them to rely heavily on the packaged and highly processed foods that dominate grocery store shelves in their communities.

24. CFS member Sally Drew's control over her food choices has been severely constrained since she moved into a continuous care community to access necessary care for her husband after he suffered a stroke. Most of Sally's meals are prepared in the care facility's kitchen and delivered to her in plastic takeout containers, and she is very concerned that the food is contaminated with phthalates from the takeout packaging as well as the ingredients the kitchen uses.

25. Many of Plaintiffs' members and supporters, such as Defend Our Health supporter Laura Seaton and ACAT supporter Margaret Yellow Wolf Tarrant, rely on school meals programs to provide lunch for their children on school days. While many of Plaintiffs' members are aware that cafeteria foods often are highly processed and tend to have higher levels of phthalates compared to foods prepared at home, they depend on these free and convenient meals provided at school to feed their children.

26. Ultimately, given the dizzying array of food products in which phthalates have been detected—from fast food meals to olive oil—even Plaintiffs' members and supporters who have the time and financial resources to prepare many of their meals from scratch from a broader array of ingredient choices still experience exposure to phthalates in their diet. Indeed, phthalate contamination has been detected even in foods certified as organic or marketed as natural.

27. Despite these challenges, many of Plaintiffs' members and supporters invest substantial time and money attempting to reduce their exposure to phthalates in their diet however they can.

28. For example, Defend Our Health supporter Laura Seaton regularly invests extra time and money to make pizza from scratch because she is concerned about phthalates and other chemicals in frozen pizza. She avoids purchasing other frozen foods that her partner and children enjoy because of these concerns.

29. Similarly, CSPI member Jean Bissell spends considerable time and money preparing foods from scratch using as many higher-end grocery products as possible in an attempt to reduce her exposure to phthalates and other concerning chemicals in her food.

30. CEH supporter Rachel Doughty invests time and money preparing lunches for her two children on school days because she is concerned about phthalates and other chemicals in the free meals available in her children's school. Rachel is concerned that the substantial number of children who depend on free or reduced-priced breakfast, lunch, and snack from the school are exposed to phthalates and other hazardous chemicals through these meals multiple times each school day, and she has volunteered for several years to advocate for safer food ware that would reduce this chemical exposure as well as plastic waste.

31. Like many of Plaintiffs' members and supporters, Laura, Jean, and Rachel experience stress or anxiety when shopping for, and preparing, food knowing that there are phthalates in many grocery products but lacking adequate information or resources to avoid these chemicals.

32. Plaintiffs' members and supporters and their children include many individuals who are particularly susceptible to harm from dietary exposure to phthalates, including infants, children, pregnant people, and people who wish to have children.

33. For example, LDA member Alexandra Moulton has two young children. She is worried that her young children are experiencing dangerous levels of phthalate exposure through their diet that could harm their brain development, and she experiences frustration and stress knowing that she is unable to protect them from this exposure on her own so long as phthalates are FDA-approved for use in so many food packaging and processing materials. Alexandra's older child experiences sensory integration and processing issues as well as symptoms of attention deficit hyperactivity disorder, which is linked to phthalate exposure. Alexandra is worried that the chemicals her son is exposed to in his food could be affecting the health of his brain.

34. Defend Our Health member Laura Seaton's son was born with hypospadias, a birth defect that also is linked to exposure to phthalates and other endocrine-disrupting chemicals and necessitated surgical intervention with a painful recovery when her son was an infant. Laura is concerned that her son's condition was caused by her unknowingly consuming phthalates and being exposed to other endocrine-disrupting chemicals during her pregnancy, and she worries about how ongoing exposure to these chemicals could affect her health and her children's health.

35. BCPP supporter Debra Cole is a breast cancer survivor and invests significant time educating herself about potential sources of exposure to endocrine-disrupting chemicals like phthalates and ways to avoid them. She is concerned that despite her efforts, exposure to phthalates in her diet could increase her risk for a recurrence of cancer and that phthalates in

food are increasing the breast cancer risks for her two daughters, who already face heightened risk because of their family health history.

36. The ongoing dietary exposure to FDA-approved phthalates experienced by Plaintiffs' members and supporters and their children increases their risks of serious and irreversible harm to their health, including but not limited to birth defects, infertility, miscarriage, and neurodevelopmental harm that is linked to learning and behavioral disorders.

37. In addition, Plaintiffs' members and supporters experience stress and anxiety as a result of this exposure and their inability to prevent this exposure through the foods they eat and feed to their children.

38. As a result of FDA's continued authorizations for uses of phthalates in food packaging and processing materials, Plaintiffs' members and supporters also are forced to spend time and money attempting to reduce their exposure to phthalates and their children's exposure by avoiding more affordable foods that they enjoy and preparing more foods from scratch using higher-priced ingredients that are less processed and have less packaging.

39. These are actual, concrete injuries that are traceable to FDA's 2022 denial of the 2016 citizen petition, which requests that FDA prohibit the use of eleven phthalates in food packaging and processing materials and address the cumulative effect of all FDA-approved phthalates in the diet, as well as FDA's 2023 denial of Plaintiffs' subsequent petition for reconsideration. If FDA reversed these decisions on remand and restricted food contact use of phthalates as Plaintiffs advocate, Plaintiffs' members and supporters and their children would no longer be exposed through their diet to numerous phthalates that are linked to serious and irreversible harm to human health and are known to leach out of food packaging and processing materials into food and beverages that they regularly consume.

40. Defendant FDA is the federal agency charged with implementing the Food Act, including its provisions to ensure the safety of substances added directly or indirectly to food.

41. Defendant Dr. Robert Califf is the Commissioner of the FDA and is sued in his official capacity.

LEGAL BACKGROUND

42. The Food Act's primary purpose is "to protect the health and safety of the public at large." *POM Wonderful, LLC v. Coca-Cola Co.*, 573 U.S. 102, 108 (2014) (citations omitted). The statute directs FDA to "protect the public health by ensuring that . . . foods are safe." 21 U.S.C. § 393(b)(2)(A).

43. As a core part of this mandate, FDA has a statutory duty to ensure the safety of all food additives, *id.* § 348(a), which include substances added directly to food as well as substances used in food packaging or processing materials that "may reasonably be expected" to migrate into food, *id.* § 321(s); *see also id.* § 348(a)(3); 21 C.F.R. § 170.3(e)(1). FDA refers to substances in the latter category as "food contact substances." *See* 21 C.F.R. § 170.3(e)(1), (3).

44. All new food additives, and new uses of existing additives, are presumed to be unsafe and their use prohibited unless their manufacturer provides adequate evidence to FDA to establish "that the proposed use of the food additive . . . *will be safe*." 21 U.S.C. § 348(c)(3)(A) (emphasis added); *see id.* § 348(h)(1) (affirming that this safety standard applies to food contact substances). To satisfy this standard, the evidence before FDA must be sufficient to support "a reasonable certainty in the minds of competent scientists that the substance is not harmful under the conditions of its intended use," 21 C.F.R. § 170.3(i), meaning the substance will not "injure or otherwise damage the health of individuals consuming the additive," Final Rule, Food

Additives Permitted for Direct Addition to Food for Human Consumption; Olestra, 61 Fed. Reg. 3,118, 3,119 (Jan. 30, 1996).

45. In determining whether a substance satisfies this safety standard, FDA must consider, "among other relevant factors," (1) "the probable consumption of the additive and of any substance formed in or on food because of the use of the additive"; (2) "the cumulative effect" of the additive in the diet, "taking into account any chemically or pharmacologically related substance or substances in [the] diet"; and (3) scientifically accepted "safety factors" to provide an appropriate margin of safety for human health where FDA is relying on health and safety studies conducted in animals. 21 U.S.C. § 348(c)(5).

46. So-called "prior-sanctioned substances," which FDA approved for direct or indirect addition to food before September 6, 1958, are excluded from the statutory definition of "food additives." *Id.* § 321(s)(4); 21 C.F.R. § 181.1(a). FDA is nonetheless obligated to ensure that prior-sanctioned substances are not used in a manner that could harm human health. *See* 21 C.F.R. § 181.1(b) (requiring FDA to restrict or prohibit the use of prior-sanctioned substance where data or information show that the substance's use "may be injurious to health").

47. FDA's regulations also affirmatively prohibit the use of specified substances as direct food additives or food contact substances for which FDA has made "a determination that they present a potential risk to the public health or have not been shown by adequate scientific data to be safe for use in human food." *Id.* § 189.1(a); *see id.* §§ 189.5–189.301. These regulations are commonly referred to as "Part 189 prohibitions."

48. The Food Act and FDA regulations provide two vehicles for petitioning FDA to modify its regulations governing substances added directly or indirectly to food. First, any person may file a "food additive petition" requesting that FDA amend or repeal a food additive

authorization. *See* 21 U.S.C. § 348(b)(1); 21 C.F.R. § 171.1; *In re Nat. Res. Def. Council*, 645 F.3d at 402–03. The Food Act requires FDA to issue a final decision granting or denying a food additive petition within ninety days of accepting the petition for filing, though the agency may extend this deadline by up to ninety days if necessary by providing written notice to the petitioner before the default ninety-day period expires. *See* 21 U.S.C. § 348(c)(2); 21 C.F.R. § 171.100. The statute does not authorize FDA to delay final action on a food additive petition beyond 180 days under any circumstances. *See* 21 U.S.C. § 348(c)(2) (requiring that FDA's decision granting or denying petition "shall be issued . . . not more than one hundred and eighty days after the date of filing of the petition"); 21 C.F.R. § 171.100(c).

49. "The second method to request amendment or repeal of a food additive regulation," or ask FDA to promulgate a new regulation banning the use of a particular substance in food, "is by citizen petition." *In re Nat. Res. Def. Council*, 645 F.3d at 403; *see* 21 C.F.R. §§ 10.30, 189.1(c). Within 180 days of receiving a citizen petition, FDA must issue a response that either grants, denies, or dismisses the petition or "[p]rovide[s] a tentative response, indicating why the agency has been unable to reach a decision on the petition, e.g., because of the existence of other agency priorities, or a need for additional information." 21 C.F.R. § 10.30(e)(2). FDA's decision on a citizen petition must be based on the information in the administrative record, *id.* § 10.30(j), which includes, among other things, both the citizen petition and the information on which it relies, as well as comments and accompanying information FDA receives on the petition, *id.* § 10.30(i).

50. A citizen petition seeking a Part 189 prohibition must "include an adequate scientific basis to support the petition" and will be published for public comment if it "contains reasonable grounds" for the action requested. *Id.* § 189.1(c). However, "the petitioner does not

bear the burden of establishing that an additive is safe or unsafe." *In re Nat. Res. Def. Council*, 645 F.3d at 403.

51. If FDA denies a food additive petition, the Food Act allows "any person adversely affected" by that decision to file objections to the denial order and request a public hearing on those objections. 21 U.S.C. § 348(f)(1). FDA must hold a public hearing "as promptly as possible," and then, "[a]s soon as practicable after completion of the hearing," FDA "shall by order act upon such objections." *Id.*

52. Any person who is adversely affected by an FDA order on such objections may file suit either in the U.S. Court of Appeals for the D.C. Circuit or in the Circuit where the adversely affected person resides or has their principal place of business. *Id*. § 348(g)(1).

53. If FDA denies a citizen petition, an "interested person may request reconsideration" of that denial. 21 C.F.R. § 10.33(b). The FDA Commissioner may grant a petition for reconsideration if he determines that doing so "is in the public interest and in the interest of justice," and he "shall" grant a reconsideration petition if:

(1) The petition demonstrates that relevant information or views contained in the administrative record were not previously or not adequately considered.
(2) The petitioner's position is not frivolous and is being pursued in good faith.
(3) The petitioner has demonstrated sound public policy grounds supporting reconsideration.
(4) Reconsideration is not outweighed by public health or other public interests.

Id. § 10.33(d).

54. FDA's final decisions on a citizen petition and on a petition for reconsideration each constitute reviewable final agency action. *Id*. § 10.45(d). However, unlike the denial of objections concerning a food additive petition, which is reviewed in the Court of Appeals, challenges to the denial of a citizen petition are reviewable only in district court. *In re Nat. Res. Def. Council*, 645 F.3d at 402, 406–07.

FACTUAL BACKGROUND

I. THE DANGERS TO HUMAN HEALTH FROM EXPOSURE TO PHTHALATES IN FOOD

55. Phthalates are a class of chemicals with similar chemical structures and similar processes through which they are metabolized in the human body. For decades, FDA has authorized the use of numerous phthalates in plastic and paperboard food packaging and a variety of food processing materials, such as plastic tubing for collecting milk at dairies, conveyer belts in food processing facilities, and food handling gloves worn by workers in food processing facilities and restaurant kitchens. The most common reason phthalates are added to these materials is to make rigid plastic components more flexible.

56. Because phthalates do not chemically bind to the materials to which they are added, they are known to leach out of food packaging and processing materials into the food and beverages they touch. As a result, people in the United States—including children—are primarily exposed to phthalates through their diet.

57. Decades of scientific research link phthalate exposure to serious health problems, and leading experts have identified human exposure to phthalates in food as an urgent public health problem. Phthalates are known endocrine disruptors, meaning they interfere with critical processes in the human body that are regulated by hormones. Among other adverse health effects, phthalate exposure is associated with serious reproductive harms to both women and men, including infertility, pregnancy complications, miscarriages, and birth defects involving abnormal development of the male reproductive tract. Phthalate exposure also is associated with the development and increased severity of uterine fibroids, more severe perimenopausal symptoms, and other health effects in women of reproductive age and beyond.

58. Further, a growing body of evidence links phthalate exposure—particularly among pregnant women, infants, and young children—with irreversible damage to brain development. Phthalates are known to transfer from a pregnant woman's blood into her developing fetus. Phthalates have been detected in maternal urine, fetal cord blood, placental tissue, and amniotic fluid, indicating exposure to the developing fetus through the pregnant mother. This exposure *in utero* can damage the developing brain, placing children at higher risk of behavioral disorders, learning disabilities, and reduced IQ.

59. Exposure to phthalates in early childhood also is linked with potentially life-altering effects on brain development, including impaired cognitive and psychomotor development, reduced social responsiveness (including difficulty making eye contact or smiling), and poorer working memory.

60. Contamination of food and beverages with phthalates added to food packaging and processing materials increases with prolonged contact between the food and the phthalate-containing material (as occurs in highly processed, shelf-stable foods); when food is heated in phthalate-containing materials; and in higher-fat foods such as milk and other dairy products, meats, and cooking oils. Higher levels of phthalate exposure are also associated with more frequent consumption of restaurant, takeout, and cafeteria meals, as well as highly processed foods including infant formula.

61. At the same time, large-scale studies in North America and other regions indicate that certain phthalates can be found in most sampled foods—including baked goods, grains, boxed macaroni and cheese, milk and other dairy products, meats, seafood, spices, cooking oils, canned fruits and vegetables, and other products. Foods certified as organic can also contain phthalates.

62. As a result, human exposure to phthalates is effectively ubiquitous. Biomonitoring studies, which measure specific chemicals and their breakdown products in human blood or urine, have demonstrated that nearly 100% of people in the United States—including children—have measurable levels of at least one phthalate in their body.

63. At the same time, certain populations are exposed to higher levels of phthalates than the general population and are more susceptible to harm from this exposure. For example, Black and Latina women of reproductive age experience disproportionately high exposure to phthalates and are more likely to suffer from health harms associated with this exposure.

64. In addition, children, infants, and developing fetuses experience higher levels of phthalate exposure than older people and are more susceptible to irreversible harm from this exposure during the critical developmental periods *in utero* and in early childhood.

65. In light of the widespread use of phthalates in food packaging and processing materials and FDA's authorization of these uses for nine different phthalates, it is impossible for most people in the United States to avoid exposure to phthalates in their food, or the food they feed their children, through their own food choices.

66. Moreover, companies are not required to disclose the presence of phthalates on food packaging or restaurant menus. As a result, consumers are left to guess whether and to what extent these chemicals may be in the food they are buying, eating, and feeding to their families.

II. THE 2016 PETITIONS TO RESTRICT THE USE OF PHTHALATES IN FOOD PACKAGING AND PROCESSING MATERIALS

67. FDA regulations currently authorize the use of nine phthalates in food packaging and processing materials, including in plastic and paperboard food packaging, adhesives, inks, equipment sanitizers, and numerous other materials from which the chemicals can leach into

food and beverages.[1] FDA regulations authorize the use of five of these phthalates as "prior-sanctioned substances." *See* 21 C.F.R. § 181.27.

68. In light of the growing body of evidence linking phthalates to serious and irreversible harms to human health, on March 18, 2016, the Food Safety Groups submitted a food additive petition to FDA requesting that the agency (1) repeal all of its existing regulations authorizing food additive uses of phthalates, and (2) promulgate new regulations prohibiting future food contact uses of eight phthalates that the Consumer Product Safety Commission's expert panel on phthalates concluded in 2014 are unsafe or likely to cause developmental harm. *See* Nat. Res. Def. Council et al., *Food Additive Petition Regarding 30 Ortho-Phthalates Submitted to FDA Pursuant to 21 USC § 348* (Mar. 18, 2016) (Ex. 1 to Declaration of Tom Neltner, ECF No. 1-1).[2]

69. The food additive petition presented substantial evidence affirmatively demonstrating the health hazards of numerous FDA-approved phthalates, cited the lack of safety data for many of the other approved phthalates that have similar properties to the more studied substances, and presented evidence that dietary exposure to phthalates is endangering human health, including among pregnant people and children. The food additive petition argued that FDA could no longer conclude with reasonable certainty that the approved phthalates are safe for use in the food contact applications the agency has authorized. Therefore, the petition requested

[1] *See* 21 C.F.R. §§ 175.105, 175.300, 175.380, 175.390, 176.170, 176.180, 176.210, 176.300, 177.1010, 177.1200, 177.1210, 177.1400, 177.2600, 178.3740, 178.3910, 181.27.

[2] The original petition addressed FDA's authorizations for thirty chemicals, but the Food Safety Groups subsequently agreed to narrow the scope of the petition to cover twenty-eight phthalates that were FDA-approved for food contact use as of 2016. *See* Letter from Breast Cancer Fund et al. to Dr. Kelly Randolph, FDA, Re: Food Additive Petition No. 6B4815 Regarding Ortho-Phthalates/Preliminary Response to Sept. 1, 2016 Request, at 2 (Oct. 8, 2016) (Neltner Decl., Ex. 7).

that FDA repeal those authorizations and promulgate new regulations prospectively banning any food contact use of the eight phthalates determined to be unsafe by the Consumer Product Safety Commission's expert panel.

70. On April 12, 2016, FDA notified the Food Safety Groups that it was accepting for filing the portion of the food additive petition asking FDA to revoke its existing regulations authorizing food additive uses of phthalates. Letter from Dr. Francis Lin, FDA, to Tom Neltner, EDF, Re: Food Additive Petition (FAP) No. 6B4815 (Apr. 12, 2016) (Neltner Decl., Ex. 2). FDA did not accept for filing the portions of the food additive petition asking FDA to (1) promulgate new regulations banning future food contact uses of the eight phthalates determined to be unsafe by the Consumer Product Safety Commission's expert panel, and (2) revoke FDA's authorizations for five phthalates that are on FDA's list of prior-sanctioned substances.

71. Instead, FDA asserted that the Food Safety Groups had to resubmit these two requests in a separate citizen petition. The Food Safety Groups objected to the agency's position regarding the proper scope of a food additive petition, but nonetheless protectively resubmitted these two requests in a citizen petition on April 19, 2016. *See* Breast Cancer Fund et al., *Citizen Petition Requesting That FDA Remove its Prior Sanction of Five Ortho-Phthalates and Ban Eight Ortho-Phthalates* (Apr. 19, 2016) (Neltner Decl., Ex. 3).

72. The 2016 citizen petition requested that FDA promulgate regulations prohibiting food contact uses of the eight phthalates that the Consumer Product Safety Commission's expert panel concluded are demonstrably unsafe or likely to cause developmental harm. The petition also requested that FDA strike its authorizations for use of five phthalates that are on FDA's list of prior-sanctioned substances. The citizen petition included the food additive petition as an

attachment and incorporated by reference the relevant reasoning and evidence set forth in the food additive petition.

73. On April 20, 2016, FDA sent the Food Safety Groups a written acknowledgment that it had received the citizen petition and assigned the petition a filing date of April 20, 2016. *See* Letter from Dynna Bigby, FDA, to Nancy Buermeyer, Breast Cancer Fund (Apr. 20, 2016) (Neltner Decl., Ex. 4).

74. On October 11, 2016, FDA sent the Food Safety Groups a letter advising that FDA had "not reached a decision on [the] petition within the first 180 days due to competing agency priorities" but that the petition was "currently under active evaluation by . . . staff." Letter from Dr. Dennis M. Keefe, FDA, to Nancy Buermeyer, Breast Cancer Fund (Oct. 11, 2016) (Neltner Decl., Ex. 9).

75. By December 2021, more than five and a half years after FDA accepted the 2016 petitions for filing, FDA still had not made a decision on either the food additive petition or the citizen petition. Thus, on December 7, 2021, Plaintiffs filed two lawsuits to compel FDA to make those overdue decisions: a petition for writ of mandamus in the U.S. Court of Appeals for the D.C. Circuit seeking to compel a decision on the food additive petition, and a complaint in this Court, filed in the instant action, challenging FDA's unreasonable delay in responding to the citizen petition. Both lawsuits requested a court order directing FDA to respond to the petition at issue within sixty days.

76. On February 9, 2022, Defendants moved to stay the proceedings in this Court until the earlier of July 19, 2022, or the date on which they issued a final decision on the citizen petition. Plaintiffs did not oppose Defendants' motion, and the Court granted it, staying the case pending further order of the Court.

77. On the same date, Defendants filed an unopposed motion in the D.C. Circuit to hold the mandamus proceedings in abeyance until the earlier of May 19, 2022, or the date on which FDA issued its decision on the food additive petition. The D.C. Circuit granted that motion and directed the case be held in abeyance pending further order of that court.

78. Meanwhile, the docket for the citizen petition remained open, and interested organizations and individuals, including scientists who study phthalates, continued to submit for FDA's consideration an ever-growing body of evidence of the harms that phthalates cause to human health. Under FDA's regulations, this information is included in the administrative record for the citizen petition and the subsequent petition for reconsideration. 21 C.F.R. §§ 10.30(i)–(j), 10.33(k).

III. FDA'S 2022 DENIALS OF THE 2016 PETITIONS AND RELATED ACTIONS CONCERNING FOOD CONTACT USES OF PHTHALATES

79. In May 2022, FDA issued four decisions concerning the use of phthalates in food contact materials that are relevant to this case. First, FDA signed a final rule revoking FDA's authorizations for obsolete uses of certain phthalates as food additives in response to a petition submitted by the Flexible Vinyl Alliance, a plastics industry trade association. Final Rule, Indirect Food Additives: Adhesives and Components of Coatings; Paper and Paperboard Components; Polymers; Adjuvants, Production Aids, and Sanitizers, 87 Fed. Reg. 31,080 (May 20, 2022). This decision was not based on a safety review but rather industry's assertion that they have abandoned the previously approved food additive uses of those specific phthalates such that FDA authorization is no longer needed. *See id.* at 31,085 (explaining that "an amendment or revocation based on abandonment is not based on safety"); 21 C.F.R. § 171.130(b) (allowing a petition to amend or repeal food additive regulations on the grounds that the regulations cover "old uses abandoned" by industry).

80. As a result of FDA's decision on this so-called "abandonment petition," nine phthalates remain affirmatively authorized for use in food contact materials under FDA's regulations, all of which are addressed in the Food Safety Groups' citizen petition and/or food additive petition. Those chemicals are: diethyl phthalate, ethylphthalyl ethyl glycolate, diallyl phthalate, butylphthalyl butyl glycolate, dicyclohexyl phthalate, diisooctyl phthalate, di(2-ethylhexyl) phthalate, diisononyl phthalate, and diisodecyl phthalate.

81. Notwithstanding industry's abandonment of certain phthalates for food contact use, phthalate contamination remains widespread in popular food items, including infant formula and other foods marketed for children, with recent research detecting phthalates addressed in the citizen petition in 100 percent of sampled foods. Roopa Krithivasan et al., *Analysis of Ortho-Phthalates and Other Plasticizers in Select Organic and Conventional Foods in the United States*, 33 J. Exposure Sci. Env't Epidemiology 778 (2023), https://doi.org/10.1038/s41370-023-00596-0.

82. Second, in a decision transmitted to the Food Safety Groups on May 19, 2022, FDA denied the Food Safety Groups' 2016 food additive petition. *See* Natural Resources Defense Council, et al.; Denial of Food Additive Petition; Denial Without Prejudice of Food Additive Petition, 87 Fed. Reg. 31,066 (May 20, 2022). FDA concluded that "the petition does not contain sufficient data to support a finding that there is no longer a reasonable certainty of no harm from the currently approved uses" of phthalates in food contact materials. *Id.* at 31,075. In so doing, FDA adopted an erroneous interpretation of what constitute "chemically or pharmacologically related" chemicals under the Food Act's safety standard and failed to consider whether any of the phthalates that remain approved for food contact use are related under this

standard, which would require FDA to consider the cumulative risks to a person's health from consuming multiple related phthalates. 21 U.S.C. § 348(c)(5)(B).

83. Third, by letter dated May 12, 2022, and transmitted to the Food Safety Groups on May 19, 2022, FDA also denied the citizen petition, incorporating by reference its decision denying the food additive petition. *See* Letter from Leslie Kux, FDA, to Nancy Buermeyer, Breast Cancer Prevention Partners, & Tom Neltner, Env't Def. Fund 2 n.3, 11 (May 12, 2022) (attached as Exhibit 1 to accompanying Declaration of Katherine O'Brien ("O'Brien Decl.")). In its letter denying the citizen petition, FDA asserted that the citizen petition and supporting evidence in the administrative record did not demonstrate that the eight phthalates for which the petition requests Part 189 prohibitions are unsafe to consume in any amount and that the petitioners failed to quantify a safe level of consumption for each of the eight phthalates at issue. *See id.* at 6–7, 10. FDA further asserted that the petitioners failed to prove that use of the prior sanctioned phthalates "may render food injurious to health at any level of exposure, or even at specified levels of exposure caused by the prior sanctioned uses." *Id.* at 11.

84. Neither FDA's decision denying the citizen petition nor its decision denying the food additive petition—on which the citizen petition denial relies—contains a determination that any of the phthalates addressed in the petitions are safe to use in food contact materials under the governing statutory and regulatory standards and in light of the hazard and exposure information presented to FDA. Nothing in FDA's decisions or the administrative record indicates that FDA reassessed the safety of these phthalates in response to the 2016 petitions.

85. FDA's final phthalate-related action in May 2022 was to issue a "request for information" related to the use of phthalates in food contact materials. *See* Ortho-phth[a]lates for Food Contact Use; Request for Information, 87 Fed. Reg. 31,090 (May 20, 2022). In that

request, FDA explained that its authorizations for the use of phthalates in food contact materials are "based on exposure and toxicological information and data provided during the period of 1961 through 1985," *i.e.*, thirty-eight to sixty-two years ago. *Id.* at 31,091. FDA requested that the public provide FDA with scientific data on the food contact uses, use levels, dietary exposure, and safety of phthalates used in food contact materials, and stated that FDA "*may* use this information to update the dietary exposure estimates and safety assessments" for these chemicals. *Id.* (emphasis added). FDA's information request did not provide any timeline for when this new safety review might occur. It also did not explain the agency's views on why it was appropriate to defer that potential safety review to some indeterminate future date, rather than conducting it in response to the food additive and citizen petitions that FDA had been considering since 2016.

IV. PLAINTFFS' REQUESTS FOR RECONSIDERATION OF FDA'S DENIALS OF THE 2016 PETITIONS

86. Following FDA's 2022 denials of the 2016 citizen petition and food additive petition, Plaintiffs sought relief from those decisions through the administrative reconsideration processes applicable to each decision under the Food Act and FDA's regulations.

87. On June 21, 2022, Plaintiffs timely petitioned for reconsideration of the citizen petition denial as provided by 21 C.F.R. § 10.33. *See* Env't Def. Fund, et al., Petition for Reconsideration, Docket No. FDA-2016-P-1171 (June 21, 2022) (attached as Exhibit 2 to O'Brien Decl.).

88. With respect to FDA's denial of both requests presented in the citizen petition, Plaintiffs argued that FDA did not adequately consider and apply the correct legal standards. Plaintiffs also argued that FDA did not adequately consider information in the administrative record, including but not limited to the Consumer Product Safety Commission's expert report on

phthalates, which concluded that the eight phthalates for which Plaintiffs seek a Part 189 prohibition pose serious health hazards and that diet is the primary way that the populations most vulnerable to harm—infants, children, and pregnant people—are exposed to many of these phthalates. In addition, Plaintiffs argued that FDA failed to adequately consider dozens of peer-reviewed studies concerning the health hazards of, and people's exposure to, the relevant phthalates that were submitted to the record by Plaintiffs and other interested parties. Plaintiffs further argued that FDA failed to consider and discharge its legal duty to assess the cumulative health risks posed by chemically and pharmacologically related phthalates in food.

89. On July 21, 2023, FDA denied Plaintiffs' reconsideration petition. *See* Letter from Lauren Roth, FDA, to Katherine K. O'Brien & Rashmi Joglekar, Earthjustice (July 21, 2023) (attached as Exhibit 3 to O'Brien Decl.). FDA asserted that the reconsideration petition did not demonstrate that relevant information or views in the administrative record were not previously or adequately considered. In support of this conclusion, FDA largely restated the arguments it made in its initial denial and again incorporated by reference its decision denying the food additive petition. FDA restated its conclusion that it need not consider the cumulative effects of dietary exposure to multiple phthalates addressed in the petition and that it need not consider the other ways that people are exposed to those phthalates when assessing whether it is safe to consume phthalates in food. FDA also affirmed its view that the requested Part 189 prohibitions are not justified because Plaintiffs did not prove that the phthalates at issue are unsafe to consume in any amount and did not quantify a safe level of exposure to each phthalate. Regarding the petition's request to revoke the prior sanctions authorizing food contact use of five phthalates, FDA claimed that the citizen petition "failed to explain any basis for concluding" that any of the five phthalates cause food to be adulterated in violation of the Food Act. *Id.* at 11.

90. FDA also insisted that it adequately considered all of the evidence in the administrative record, including the report of the Consumer Product Safety Commission's expert panel. As it did in its original petition denial, FDA asserted that the expert report's conclusions concerning the health hazards of phthalates addressed in the petition and the predominance of dietary exposure to those phthalates among vulnerable groups were not relevant to the questions before FDA because the expert report was developed to assess whether those phthalates should be restricted in toys and childcare articles, not food. Regarding the other evidence in the administrative record—which includes dozens of peer-reviewed studies on phthalates' health hazards and people's exposure published since the petition was submitted in 2016—FDA claimed the agency considered all of it, critiqued a subset of the documents presented to FDA, and restated its position that the evidence did not prove that the regulatory changes Plaintiffs seek are justified. As in the original petition denial, FDA did not determine that any of the phthalates at issue are safe for consumption in food based on the evidence before the agency.

91. On June 21, 2022, Plaintiffs also submitted timely objections to FDA's denial of the food additive petition and requested a public hearing on those objections, as provided by 21 U.S.C. § 348(f)(1) and FDA's regulations. *See* Objections and Request for Evidentiary Public Hearing Regarding FDA's Denial of Phthalates Food Additive Petition (FAP 6B4815), Docket No. FDA-2016-F-1253 (June 21, 2022) (attached as Exhibit 4 to O'Brien Decl.). Plaintiffs lodged eight objections, several of which raise issues that also were presented in the citizen petition and associated reconsideration request, including: (1) FDA's failure to apply the correct legal standards and to reevaluate the safety of the phthalates at issue in response to the evidence and arguments presented in the petition proceedings; (2) FDA's failure to adequately address toxicity and exposure information presented in the petition proceedings; and (3) FDA's failure to

consider the cumulative health risks posed by people's dietary exposure to multiple phthalates that are "chemically or pharmacologically related," 21 U.S.C. § 348(c)(5)(B), as the Food Act requires.

92. Though Plaintiffs submitted their objections approximately seventeen months ago, FDA has not yet ruled on the objections. Nor has FDA convened the requested public hearing, which the Food Act requires FDA to hold "as promptly as possible." 21 U.S.C. § 348(f)(1).

FIRST CLAIM FOR RELIEF

93. Plaintiffs incorporate by reference and re-allege all allegations set forth in the preceding paragraphs.

94. The APA directs reviewing courts to hold unlawful and set aside final agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

95. It was arbitrary, capricious, and contrary to the Food Act and FDA's regulations for FDA to deny Plaintiffs' citizen petition to revoke the prior sanctions authorizing food contact uses of five phthalates—diethyl phthalate, ethylphthalyl ethyl glycolate, butylphthalyl butyl glycolate, diisooctyl phthalate, and di(2-ethylhexyl) phthalate. *See id.*; 21 U.S.C. §§ 342, 348; 21 C.F.R. § 181.1(b). Among other defects that render FDA's decision arbitrary, capricious, and contrary to law, FDA applied the wrong legal standard for reevaluating the safety of prior sanctions, failed to rationally address substantial toxicity and exposure information in the administrative record demonstrating that these chemicals are not safe for food contact use, and failed to consider the cumulative effects of exposure to multiple related phthalates in the diet as the Food Act and FDA's regulations require.

SECOND CLAIM FOR RELIEF

96. Plaintiffs incorporate by reference and re-allege all allegations set forth in the preceding paragraphs.

97. The APA directs reviewing courts to hold unlawful and set aside final agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

98. It was arbitrary, capricious, and contrary to the Food Act and FDA's regulations for FDA to deny Plaintiffs' citizen petition to establish regulations under 21 C.F.R. Part 189 that would "prohibit[] from use in human food" the eight phthalates that the Consumer Product Safety Commission's expert panel determined are unsafe or likely to cause developmental harm—*i.e.,* butyl benzyl phthalate, diisobutyl phthalate, di-n-butyl phthalate, dicylohexyl phthalate, di-n-hexyl phthalate, diisooctyl phthalate, di(2-ethylhexyl) phthalate, and diisononyl phthalate. 21 C.F.R. § 189.1; *see also* 5 U.S.C. § 706(2); 21 U.S.C. §§ 342, 348. Among other defects that render FDA's decision arbitrary, capricious, and unlawful, FDA applied the wrong legal standard to the petitioners' request, failed to rationally consider substantial hazard and exposure information in the administrative record indicating that these chemicals are not safe for food contact use, and failed to consider the cumulative effects of exposure to multiple related chemicals in the diet as the Food Act and FDA's regulations require.

THIRD CLAIM FOR RELIEF

99. Plaintiffs incorporate by reference and re-allege all allegations set forth in the preceding paragraphs.

100. The APA directs reviewing courts to hold unlawful and set aside final agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

101. FDA's regulations require it to grant a petition for reconsideration of FDA's decision denying a citizen petition where the petitioner demonstrates that (1) FDA's decision denying the citizen petition did not adequately consider relevant information or views in the administrative record; (2) the petitioners advance a good-faith, non-frivolous position; (3) sound public policy grounds support reconsideration; and (4) reconsideration is not outweighed by public health or other public interests. 21 C.F.R. § 10.33(d).

102. It was arbitrary, capricious, and contrary to FDA's regulations for FDA to deny Plaintiffs' petition for reconsideration of FDA's 2022 denial of the Food Safety Groups' 2016 citizen petition. *See id*.

103. FDA disputed only the first of the four factors governing reconsideration petitions, *id*. § 10.33(d)(1), and its decision does not demonstrate application of the correct legal standard nor rational consideration of key evidence in the record. For example, FDA arbitrarily dismissed the conclusions of the Consumer Product Safety Commission's expert panel concerning the toxicity of relevant phthalates and the predominance of dietary exposure to those chemicals on the basis that the panel's report was developed to inform restrictions on the use of phthalates in toys and childcare articles rather than food. Additionally, FDA arbitrarily dismissed all epidemiological studies in the record, which document associations between exposure to phthalates and specific health harms, on the basis that the study subjects may have been exposed to phthalates from sources additional to food and drinks.

104. Because Plaintiffs demonstrated that FDA failed to adequately consider relevant information or views in the administrative record and that the other factors justifying reconsideration were satisfied, FDA's regulations required it to grant Plaintiffs' reconsideration petition. *Id*. § 10.33(d).

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court:

(a) Declare unlawful and set aside FDA's decision denying the 2016 citizen petition;

(b) Declare unlawful and set aside FDA's decision denying Plaintiffs' 2022 petition for reconsideration of the citizen petition denial;

(c) Remand this matter to FDA for further action consistent with this Court's opinion;

(d) Award Plaintiffs reasonable costs and attorneys' fees; and

(e) Grant such other and further relief as the Court deems just and proper.

Respectfully submitted this 22nd day of November, 2023.

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