

**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
1220 L Street NW, Suite 300
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.
JANET WOODCOCK, in her official capacity as Acting
Commissioner of the U.S. Food and Drug Administration,

Defendants.

Case No.

**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. Janet Woodcock, Acting Commissioner of the FDA (collectively, “Defendants” or “FDA”).

2. Plaintiffs seek relief from FDA’s years-long delay in responding to a 2016 citizen petition submitted by six of the Plaintiffs and other allied groups (collectively, the “Food Safety Groups”). The 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. It has been more than five and a half years since the Food Safety Groups petitioned FDA to take action to address the urgent public health threats posed by phthalate exposure in the diet, but FDA has failed to act. 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 years-long unreasonable delay in acting on the 2016 citizen petition, Plaintiffs seek an order from this Court directing FDA to make a final decision granting or denying the petition within sixty days.

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(1); 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 (D.C. Cir. 2011) (holding that district court possesses exclusive jurisdiction over suits to compel FDA decision on a citizen petition submitted under the Food Act). The relief requested is authorized by 5 U.S.C. § 706(1) and 28 U.S.C. §§ 2201–2202.

7. Venue is proper in this Court under 28 U.S.C. § 1391(e)(1)(C) because Plaintiffs Center for Food Safety and Center for Science in the Public Interest have their 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 failure to act on the 2016 citizen petition, 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 non-profit membership organization headquartered in Washington, D.C. 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 fourteen board members and its network of more than 30,000 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 400,000 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 has members, board members, staff, and/or other supporters who have been harmed by FDA's delay in acting on the 2016 citizen petition and will continue to be harmed so long as FDA withholds a decision.

18. 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.

19. For example, CSPI member Jean Bissell and her husband regularly consume several gallons of milk per week. ACAT staff member 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.

20. 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.

21. 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.

22. 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.

23. 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.

24. Many of Plaintiffs' members and supporters, such as Defend Our Health supporter Laura Seaton and ACAT staff member 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.

25. 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.

26. 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.

27. 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.

28. 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.

29. CEH supporter Rachel Doughty invests time and money preparing lunches for her five- and eight-year-old 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.

30. 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.

31. 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.

32. For example, LDA member Alexandra Moulton has two young children, aged one and five years old. 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.

33. 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.

34. 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.

35. 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.

36. 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.

37. 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.

38. These are actual, concrete injuries that are traceable to FDA's failure to act on 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. If FDA is required to act and makes a final decision granting the petition, 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. Alternatively, if FDA made a final decision denying the petition, that would allow Plaintiffs to pursue remedies before the agency and in the courts that are not available so long as FDA withholds a final decision.

39. 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.

40. Defendant Dr. Janet Woodcock is the Acting Commissioner of the FDA and is sued in her official capacity.

LEGAL BACKGROUND

41. 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).

42. 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).

43. 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).

44. In determining whether a substance satisfies this safety standard, FDA must consider (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).

45. 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”).

46. 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.

47. 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).

48. “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).

49. Further, the APA requires each federal agency “to conclude a matter presented to it” “within a reasonable time.” 5 U.S.C. § 555(b). A “reviewing court shall . . . compel agency action” that has been “unreasonably delayed.” *Id.* § 706(1).

FACTUAL BACKGROUND

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

50. 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.

51. 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.

52. 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.

53. 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.

54. 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.

55. 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.

56. 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.

57. 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.

58. 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.

59. 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.

60. In light of the widespread use of phthalates in food packaging and processing materials and FDA's authorization of these uses for more than two dozen 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.

61. 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

62. FDA regulations currently authorize the use of twenty-eight 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.

63. 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).²

64. 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

¹ *See* 21 C.F.R. §§ 175.105, 175.300, 175.320, 175.380, 175.390, 176.170, 176.180, 176.210, 176.300, 177.1010, 177.1200, 177.1210, 177.1400, 177.1460, 177.1590, 177.2420, 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. *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).

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 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.

65. 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.

66. 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).

67. 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.

68. 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).

69. 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).

70. FDA has not sent the Food Safety Groups any correspondence regarding their citizen petition since October 11, 2016, and FDA has not provided a substantive response to the petition in the five years, seven months, and seventeen days since it accepted the petition for filing.

CLAIM FOR RELIEF

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

72. The APA requires that an agency “shall . . . conclude a matter presented to it” “within a reasonable time,” 5 U.S.C. § 555(b), and the reviewing court “shall . . . compel agency action . . . unreasonably delayed,” *id.* § 706(1).

73. More than five years and seven months have passed since FDA accepted the Food Safety Groups’ citizen petition for filing, yet FDA has failed to issue a final decision granting or denying the petition.

74. As a result, Plaintiffs’ members and supporters and their children have experienced years of unnecessary exposure to phthalates in their food and beverages, placing them at heightened risk of developing serious and permanent health harms, including reproductive and neurodevelopmental harms. These health burdens fall disproportionately on babies and young children undergoing critical periods of growth and development, Black and Latino people, and people of low wealth.

75. Although there is substantial scientific evidence demonstrating the dangers to human health from dietary exposure to the phthalates addressed in the citizen petition and related substances, these substances remain in widespread use in food packaging and processing materials pursuant to FDA authorizations, leading to contamination of countless food products—from milk and infant formula to snack foods and restaurant meals—with phthalates. Because phthalates’ presence in these foods is so widespread and is not disclosed on packages or restaurant menus, Plaintiffs’ members and supporters are not able to avoid exposure to themselves or their children through their individual food choices. This is particularly true for Plaintiffs’ members and supporters whose food choices are constrained because of their financial circumstances, their reliance on school meals programs to feed their children, limited food options in their communities, and other factors.

76. Plaintiffs' members and supporters will continue to experience this harm so long as FDA refuses to act on the petition. Further, so long as FDA withholds a final decision on the petition, Plaintiffs have no recourse before the agency and cannot obtain judicial review on the merits of the issues the petition raises.

77. FDA has provided no public justification for its failure to act on this urgent public health problem for more than five and a half years. FDA's years-long delay in issuing a decision on the petition is unreasonable, violates the APA, and warrants relief from this Court. 5 U.S.C. §§ 555(b), 706(1).

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court:

- (a) Declare that FDA's failure to respond to the 2016 citizen petition violates the APA's mandate that an "agency shall proceed to conclude a matter presented to it" "within a reasonable time," 5 U.S.C. § 555(b), and constitutes "unreasonabl[e] delay[]," *id.* § 706(1);
- (b) Order FDA to issue a final order granting or denying the citizen petition within sixty (60) days;
- (c) Retain jurisdiction over this matter until Defendants have fulfilled their statutory and Court-ordered obligations;
- (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 7th day of December, 2021.

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