IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

NATURAL RESOURCES DEFENSE COUNCIL, INC., BREAST CANCER PREVENTION PARTNERS, CENTER FOR ENVIRONMENTAL HEALTH, CENTER FOR FOOD SAFETY, ENVIRONMENTAL DEFENSE FUND, and ENVIRONMENTAL WORKING GROUP, Plaintiffs, v. U.S. FOOD AND DRUG ADMINISTRATION; and NORMAN E. SHARPLESS, in his official capacity as acting commissioner of the Food and Drug Administration, Defendants.	)	Case No. _____

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

INTRODUCTION

1. Plaintiffs Natural Resources Defense Council (NRDC), Breast Cancer Prevention Partners (BCPP), Center for Environmental Health (CEH), Center for Food Safety (CFS), Environmental Defense Fund (EDF), and Environmental Working Group (EWG) (together, Plaintiffs) petitioned the Food & Drug Administration (FDA or the Agency) to ban the use of a dangerous chemical, perchlorate, in materials that contact food. FDA denied the petition, relying on flawed reasoning while entirely ignoring important evidence and arguments that

necessitate the ban. Plaintiffs challenge the Agency's arbitrary and unlawful petition denial.

2. Perchlorate is a chemical compound used as a propellant in rocket fuel. It is also used as an additive in plastic packaging and other food-contact articles to reduce the buildup of static charges resulting from the movement of dry foods, like cereal, flour, and spices.

3. Perchlorate exposure through food is harmful to human health. Exposure is particularly dangerous for fetuses, infants, and young children, as it has been linked to developmental delays, reduced growth, and impaired learning capabilities.

4. In 2005, FDA approved the use of perchlorate in certain food packaging.[1]

5. Since this approval, FDA's own research demonstrates that levels of perchlorate concentration in a number of foods, including baby food, have spiked to significantly higher levels, well in excess of pre-approval results.

6. In many cases, perchlorate is present in foods at levels that substantially increase the probability of serious harm.

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[1] FDA has repeatedly revised its own description of the uses authorized by the approval Plaintiffs challenge. At times, FDA has appeared to limit the use of perchlorate to "food packaging." At other times, FDA has appeared to allow the use of perchlorate in both food packaging and "polymeric food articles," i.e. plastic materials that contact food. Plaintiffs' petition sought the revocation of this approval in its entirety, whether it is limited to food packaging or expanded to include all food-contact articles. In this Complaint, Plaintiffs refer to all materials that contact food—including packaging and food-handling equipment—as "food-contact articles." *See also* 21 C.F.R. § 170.39.

7. In 2014, Plaintiffs and others petitioned FDA to revoke its authorization for the use of perchlorate in food-contact articles (the Perchlorate Petition or the Petition).

8. In 2017, FDA denied Plaintiffs' Petition (the Petition Denial).

9. In denying Plaintiffs' petition, FDA ignored its own research showing that perchlorate concentrations in foods most likely to have contacted perchlorate-containing materials had spiked in the years following the Agency's approval of perchlorate use in food-contact articles.

10. FDA also ignored the very likely possibility that foods will come into contact with multiple perchlorate-containing food-contact articles during the various stages of production, transportation, and preparation for sale, increasing the amount of perchlorate that could migrate into those foods.

11. In both respects, FDA acted arbitrarily and capriciously in violation of the Administrative Procedure Act (APA). 5 U.S.C. § 701 *et seq*.

12. FDA also failed to consider "the cumulative effect" on human health of exposure to perchlorate in food, taking into account the effects of perchlorate in combination with "any chemically or pharmacologically related substance or substances in [the] diet," as required by the Federal Food, Drug, and Cosmetic Act (the Food Act). 21 U.S.C. § 348(c)(5)(B).

13. On June 4, 2017, Plaintiffs filed objections to the Petition Denial, and in April 2019, FDA denied Plaintiffs' objections.

14. Plaintiffs therefore seek an order from this Court declaring FDA's denial of the Perchlorate Petition arbitrary, capricious, and not in accordance with the Food Act; vacating the denial; and remanding the denial to the Agency so that it may reconsider the Petition in accordance with the facts and law.

JURISDICTION AND VENUE

15. This Court has subject matter jurisdiction over this action pursuant to federal question jurisdiction, 28 U.S.C. § 1331.

16. This Court has authority to issue declaratory relief pursuant to 28 U.S.C. §§ 2201-2202.

17. The Commissioner's decision is a final agency action that is reviewable pursuant to the Administrative Procedure Act. 5 U.S.C. § 706; *see* 21 C.F.R. § 10.45.

18. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(e)(1)(C) because Plaintiffs NRDC and EDF reside in this judicial district.

THE PARTIES

19. Plaintiff NRDC is a national, not-for-profit environmental and public health organization with approximately 376,000 members, including 31,500 members in New York. NRDC engages in research, advocacy, media, and litigation related to protecting public health and the environment. For decades, NRDC has worked to safeguard the nation's food supply from harmful chemicals.

20. Plaintiff Breast Cancer Prevention Partners is a national, not-for-profit organization that engages in science-based policy and advocacy work, with the goal of preventing breast cancer by eliminating exposure to toxic chemicals and

radiation linked to the disease. BCPP represents a broad base of supporters, who—together with the fifteen independent, voting members of BCPP's Board of Directors—help to steer and fund the organization's activities.

21. Plaintiff Center for Environmental Health is a national, not-for-profit organization with approximately 36,000 supporters, including 1,800 supporters in New York. CEH works with a broad array of partners and a dedicated Board of Directors to protect people from toxic chemicals by demanding and supporting business practices that are safe for public health and the environment.

22. Plaintiff Center for Food Safety is a national, not-for-profit membership organization with approximately 950,000 members, including 30,000 members in New York. CFS's mission is to protect human health and the environment by curbing the use of harmful food production technologies, including unsafe food additives, and promoting sustainable alternatives. CFS provides oversight of governmental activities surrounding the safety of our foods and, when necessary, engages in public interest litigation to compel agencies to perform their statutory duties and protect the public and CFS members from the negative impacts of unsafe foods.

23. Plaintiff Environmental Defense Fund is a national, not-for-profit environmental and public health organization with approximately 463,000 members, including 41,000 members in New York. EDF engages in research, advocacy, media, and litigation related to protecting public health and the environment.

24. Plaintiff Environmental Working Group is a national, not-for-profit organization that works to empower people to live healthier lives in a healthier environment. EWG's work is driven and funded, in part, by its dedicated community of more than one million consumer-supporters and the twenty-one members of its Board of Directors.

25. Plaintiffs bring this action on behalf of their members.

26. Plaintiffs' members include individuals and families who eat and feed their children foods in which perchlorate has been detected and foods that have been handled or packaged with material containing perchlorate.

27. Plaintiffs and their members are injured by FDA's decision to allow the continued use of perchlorate in materials that contact food.

28. FDA's failure to comply with the Food Act has substantially increased the risk that Plaintiffs' members and their children will suffer health problems resulting from perchlorate consumption. There is broad scientific consensus that perchlorate ingestion can harm human health. Perchlorate has been detected at dangerous levels in a wide variety of foods found in stores across the country, including foods that Plaintiffs' members and their families eat on a daily basis, such as cereal marketed for consumption by infants and toddlers. Because FDA continues to allow the use of perchlorate in food-contact articles, Plaintiffs' members and their families will continue to consume foods in which perchlorate could be present. This continued risk of exposure to dangerous doses of perchlorate substantially increases the probability of serious harm to Plaintiffs' members.

29. Plaintiffs' members and their children ingest food that is likely contaminated with perchlorate on a daily basis—at home, at school, at work, at restaurants, and at other locations. There is no labeling requirement for food that has contacted perchlorate—whether in packaging for the final product, in bulk packaging for any of the ingredients, or in food-processing equipment. Plaintiffs' members therefore have no way of voluntarily protecting themselves from ingesting perchlorate through food.

30. The relief sought in this suit would require FDA to comply with its statutory obligations and would redress the harm to Plaintiffs' members.

31. Defendant FDA, a federal agency of the United States, is responsible for the implementation and administration of the relevant provisions of the Food Act.

32. Defendant Norman E. Sharpless is Acting Commissioner of the FDA. He is sued in his official capacity.

STATUTORY AND REGULATORY FRAMEWORK

The Federal Food, Drug, and Cosmetic Act

33. The Food Act "is designed primarily to protect the health and safety of the public at large." *POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102, 108 (2014).

34. As relevant here, the Food Act prohibits the introduction of any "adulterated" food into interstate commerce. 21 U.S.C. § 331(a).

35. A food is "adulterated" if it contains an "unsafe" "food additive." *Id.* § 342(a)(2)(C)(i).

36. A "food additive" includes "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food)." *Id.* § 321(s); *see also id.* § 348(h)(6) (defining subset of food additives known as "food contact substance[s]").

37. A "food additive" is "deemed unsafe," and thus food containing the additive is "adulterated," *id.* § 342(a)(2)(C), unless, as relevant here, a "regulation issued under this section prescribing the conditions under which such additive may be safely used" is "in effect," and "such substance and the use of such substance are in conformity with" that regulation. *Id.* § 348(a)(3).

38. The Food Act requires that FDA, "[i]n determining . . . whether a proposed use of a food additive is safe," consider "the cumulative effect of such additive in the diet of man or animals, taking into account any chemically or pharmacologically related substance or substances in such diet." 21 U.S.C. § 348(c)(5)(B).

39. FDA has developed an alternative mechanism—the "Threshold of Regulation" (TOR) procedures—for any food additive that migrates from a food-contact article to food itself at such low concentrations as to be "below the threshold

of regulation." 21 C.F.R. § 170.39(a). Under this FDA procedure, such food additives are not subject to the requirement under 21 U.S.C. § 348 that a food-additive regulation be in effect. *See* Food Additives; Threshold of Regulation for Substances Used in Food-Contact Articles, 60 Fed. Reg. 36,582 (July 17, 1995).

40. To qualify for a TOR exemption, the "use in question" must be "shown to result in" (or "be expected to result in") "dietary concentrations at or below 0.5 parts per billion," which FDA calculates as "corresponding to dietary exposure levels at or below 1.5 micrograms/person/day (based on a diet of 1,500 grams of solid food and 1,500 grams of liquid food per person per day)." 21 C.F.R. § 170.39(a)(2)(i).

41. Section 348(c)(5)(B) of the Food Act requires FDA, when approving a TOR exemption, to consider "the cumulative effect" of the relevant additive and related substances in the diet.

42. If FDA receives significant new information that raises questions about the dietary concentration or the safety of a substance that the Agency has exempted from regulation, the Agency may reevaluate the exemption for that substance. 21 C.F.R. § 170.39(g).

43. Any "interested person may petition the Commissioner to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action." 21 C.F.R. § 10.25. Such petition may take "the form for a citizen petition in [21 C.F.R.] § 10.30." *Id.* § 10.25(a)(2).

44. The "Commissioner's final decision" on a citizen petition submitted under 21 C.F.R. § 10.25(a) "constitutes final agency action (reviewable in the courts

under 5 U.S.C. 701 et seq. and, where appropriate, 28 U.S.C. 2201)." 21 C.F.R. § 10.45(d).

The Administrative Procedure Act

45. Under the APA, a reviewing court shall "hold unlawful and set aside" agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

46. An agency decision is unlawful under the APA "if the agency has relied on factors which Congress has not intended it to consider," has "entirely failed to consider an important aspect of the problem," has "offered an explanation for its decision that runs counter to the evidence before the agency," or "is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

FACTUAL BACKGROUND AND PROCEDURAL HISTORY

Perchlorate

47. Perchlorate is an endocrine-disrupting chemical that interferes with thyroid function. By inhibiting the thyroid's uptake of iodine, perchlorate impairs production of hormones critical to fetal and infant brain development.

48. Because thyroid hormones are critical to growth and development, fetuses, infants, and young children are particularly vulnerable to perchlorate ingestion.

49. Even transient exposures to perchlorate among pregnant women may result in permanent cognitive deficits in their children.

50. Scientific studies have linked decreased thyroid function in pregnant women, infants, and children to delayed development, reduced growth, and impaired learning capabilities.

51. Perchlorate contamination is widespread; the chemical has been found in the urine of all Americans six years and older tested as part of the ongoing National Health and Nutrition Examination Survey (NHANES). In a different survey conducted by FDA between 2003 and 2006, perchlorate was detected in the majority of 285 tested foods. In FDA's most recent study, in 2016, perchlorate contamination in food was "ubiquitous."

52. As relevant here, perchlorate is used as a component in the manufacture of antistatic agents to be used in food-contact articles.

53. Antistatic agents facilitate the flow of dry food goods. A static charge is likely to be generated when a dry solid—like flour or grain—flows. When the solid is flowing across a non-conductive material, such as a typical plastic, a static charge can accumulate. If the accumulated charge reaches a high enough level, it can produce a spark that ignites the powder and causes a dust explosion.

54. The purpose of an antistatic agent, such as one containing perchlorate, is to dissipate the charge that might otherwise accumulate from the flowing dry food. Perchlorate incorporated into the antistatic agent enhances the conductivity of the material, helping to dissipate any built-up charge.

55. As dry-food ingredients move from farms and factories to dinner tables, they are likely to contact perchlorate in many packaging and processing materials.

56. There are safer alternatives to this use of perchlorate. Carbon, for example, can be used to reduce static in dry-food packaging. Flushing packaging with carbon dioxide or nitrogen also removes static charge, thereby eliminating the need for chemical antistatic agents.

Perchlorate in the Food Supply

57. Perchlorate enters the food supply in a number of ways in addition to through food-contact articles.

58. Historically, perchlorate has been used primarily in rocket fuel, ammunition, fireworks, and explosives. Those industrial and military uses of perchlorate have released perchlorate into the environment and, ultimately, into the food supply.

59. Because perchlorate dissolves easily in water, perchlorate plumes move quickly through groundwater and surface water. As a result, perchlorate has been detected in public drinking water systems across the United States.

60. Perchlorate is also found in surface water that is used to irrigate agricultural fields. Crops take up perchlorate from irrigation water and remain contaminated with perchlorate as they are processed into food.

61. Perchlorate-contaminated water is also used to irrigate feed crops like alfalfa, which are fed to dairy cows. Dairy cows absorb perchlorate from feed, leading to perchlorate contamination in dairy products.

62. Perchlorate also enters the food supply when hypochlorite bleach, used to wash certain fruits and vegetables and as a disinfectant in food production, degrades into perchlorate as it ages. *See* 21 C.F.R. § 173.315; 40 C.F.R. §§ 180.1054, 180.1235.

63. Exposure to perchlorate is cumulative. Exposure from any one source adds to the harms from exposure from all other sources.

Substances Related to Perchlorate

64. Substances that are pharmacologically related to perchlorate also enter our food supply.

65. For example, nitrates and thiocyanates are pharmacologically related to perchlorate. Like perchlorate, they, too, inhibit iodine uptake.

66. Nitrates are widely found in food.

67. Thiocyanates are also found in some foods.

The TOR Exemption

68. On June 17, 2005, Ciba Specialty Chemicals Corporation (Ciba) submitted a request for a TOR exemption allowing for the use of sodium perchlorate monohydrate in a packaging material to be known as Irgastat P18.

69. On November 4, 2005, FDA issued TOR Exemption No. 2005-006 (the TOR Exemption).

70. The TOR Exemption authorizes the use of perchlorate as a conductivity enhancer in antistatic agents, at a maximum concentration of 4% in

the antistatic agent and 1.2% by weight in the finished article, for use in contact with dry foods.

71. Any manufacturer, not only Ciba or its successor BASF, may use perchlorate in the manner prescribed by the TOR Exemption.

FDA's Study of Perchlorate in Food

72. Since 1961, and on an ongoing basis, FDA has conducted the Total Diet Study. The study is intended to monitor the U.S. food supply for, among other things, chemical contaminants.

73. The study involves retail purchases of foods intended to be representative of the average American's "total diet," including baby food, beverages (including bottled water), dairy, eggs, fat, oil, fruits, vegetables, grains, legumes, meat, poultry, fish, and sweets.

74. FDA then analyzes those foods for hundreds of contaminants.

75. In certain federal fiscal years, FDA has analyzed certain foods for perchlorate, including baby food in fiscal year 2005, all foods other than baby foods in fiscal year 2006, and all foods again in fiscal years 2008-2012.

76. In 2008, FDA scientists published a peer-reviewed study estimating dietary intake of perchlorate and iodine from its Total Diet Study samples collected in 2005 and 2006.

77. On December 21, 2016, FDA scientists updated the 2008 study with a published, peer-reviewed analysis of Total Diet Study samples collected from 2008 to 2012.

78. On May 3, 2017, FDA published a summary of the 2016 study, including more detailed data, on its website.

79. Data from the Total Diet Study samples and FDA's 2008 and 2016 analyses of those data show that samples of dry foods collected prior to FDA's approval of the TOR Exemption have relatively low levels of perchlorate contamination. Samples of dry foods collected in the years following FDA's approval of the TOR Exemption—allowing for the use of perchlorate in food-contact articles used to store and transport dry foods—have significantly higher levels of perchlorate contamination.

80. It is unlikely that the foods in which high levels of perchlorate contamination were found were contaminated by perchlorate from any source other than packaging and processing articles authorized by the TOR Exemption.

The Perchlorate Petition

81. In 2014, Plaintiffs and other groups submitted a petition to FDA requesting that the Agency ban uses of perchlorate in materials that contact food. Specifically, the Perchlorate Petition asked FDA to:

a) Revoke its 2005 approval of the TOR Exemption, No. 2005-006, which allows sodium perchlorate monohydrate to be used in dry food packaging;
b) Promulgate a new regulation, to replace 21 C.F.R. § 189.301, prohibiting the use of perchlorate in antistatic agents to be used in food-contact articles; and
c) Revoke the food-additive regulation allowing for the use of potassium perchlorate as an additive in sealing gaskets for food containers.

82. The Perchlorate Petition identified flaws in FDA's 2005 analysis that resulted in the Agency's approval of the TOR Exemption.

83. The Perchlorate Petition also identified significant new information that called into question the safety of perchlorate.

84. On March 31, 2016, after FDA had failed to respond to the Perchlorate Petition, some of the Plaintiffs, including NRDC, BCPP, CEH, CFS, and EWG, filed a petition for a writ of mandamus in the Ninth Circuit, seeking to compel FDA to respond to the Petition. *In re Breast Cancer Fund*, No. 16-70878 (9th Cir. Mar. 31, 2016).

85. That case became moot when, on May 4, 2017, FDA issued the Petition Denial. Natural Resources Defense Council et al.; Denial of Food Additive Petition, 82 Fed. Reg. 20,847 (May 4, 2017); *see* Dkt. 15, Stipulation of Dismissal, *In re Breast Cancer Fund*, No. 16-70878 (9th Cir. May 12, 2017).

86. On June 4, 2017, Plaintiffs and others filed objections and a request for a formal evidentiary public hearing pursuant to 21 U.S.C. § 348(f). EDF et al., Objections and Request for Formal Evidentiary Public Hearing Regarding FDA's Denial of Perchlorate Food Additive Petition No. 4B808, at Docket No. FDA-2015-F-537 (June 4, 2017). On April 24, 2019, FDA denied that request. 84 Fed. Reg. 17,113 (Apr. 24, 2019).

The Petition Denial

87. The Petition Denial rejected as moot the Petition's third request—that FDA revoke the food-additive regulation allowing for the use of potassium perchlorate in food container gaskets—because FDA had granted an industry organization's petition seeking to withdraw the regulation authorizing perchlorate

use in gaskets because the industry had abandoned such use. Petition Denial, 82 Fed. Reg. at 20,849; *see* Society of the Plastics Industry, Inc.; Filing of Food Additive Petition, 81 Fed. Reg. 42,585 (June 30, 2016).

88. As to the Petition's other two requests—that FDA revoke its 2005 approval of the TOR Exemption and promulgate a new regulation to replace 21 C.F.R. § 189.301 to prohibit the use of perchlorate in antistatic agents—FDA issued a "final Agency decision" denying those requests. Petition Denial, 82 Fed. Reg. at 20,850.

FDA Ignored the Data from Its Own Total Diet Study

89. In issuing the Petition Denial, FDA ignored the results of the 2008 and 2016 peer-reviewed publications analyzing the Total Diet Study samples.

90. Data from the Total Diet Study samples and FDA's analyses showed that perchlorate concentrations in foods likely to contact perchlorate-containing materials spiked in the years following the Agency's approval of the TOR Exemption.

91. That evidence directly "raises questions about the dietary concentration" of the substance. 21 C.F.R. § 170.39(g). FDA and Ciba, the manufacturer that requested the TOR Exemption, calculated likely exposure to perchlorate resulting from the TOR Exemption. But the Total Diet Study evidence and FDA's 2016 analysis tend to show that, contrary to the assumptions underlying those calculations, the actual exposure is substantially higher.

92. FDA should have considered whether data from the Total Diet Study samples and its 2008 and 2016 analyses of those data show that the assumptions and calculations underlying the perchlorate TOR Exemption are inaccurate in reality. That is because FDA's own data and analyses show that the TOR Exemption *itself* may have meaningfully contributed to increased levels of perchlorate in dietary intake among young children.

93. Unaccountably, FDA failed to mention its own 2016 study and the underlying data in its Petition Denial.

FDA Ignored the Possibility of Multiple Exposures

94. FDA also ignored the probability that foods will come into contact with multiple perchlorate-containing food-contact articles.

95. A particular ingredient is likely to come into contact with multiple perchlorate-containing food-contact articles. A dry ingredient, like rice, may be transported in one container treated with perchlorate from field to silo and in a different container treated with perchlorate from silo to processing plant. There, it may be processed using chutes, conveyor belts, grinders, and screens treated with an antistatic agent containing perchlorate. Following processing, the ingredient may be transported again in a package containing perchlorate.

96. That ingredient will likely contain higher levels of perchlorate than if it had contacted only a single perchlorate-containing food-contact article.

97. FDA entirely failed to consider whether non-fatty, dry foods will come into contact with multiple perchlorate-containing food-contact articles.

98. Conducting such an analysis would have demonstrated that FDA's assumptions about the expected daily intake of perchlorate resulting from the TOR Exemption are flawed and substantially underestimate the rate at which perchlorate migrates into the food supply.

99. FDA did not conduct such an analysis in its Petition Denial.

FDA Refused to Analyze Cumulative Effects as Required by Law

100. There are important additional sources of perchlorate and pharmacologically related substances in the diet, including perchlorate that enters the food supply through contaminated drinking water, ground water, and surface water; perchlorate resulting from hypochlorite bleach, used to wash certain fruits and vegetables and as a disinfectant in food production; and nitrates and thiocyanates found in drinking water or used in food and materials that contact food.

101. FDA unlawfully refused to consider the cumulative effect of the use of perchlorate and pharmacologically related substances. Petition Denial, 82 Fed. Reg. at 20,854-55; *see id.* at 20,857.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF:
FDA violated the APA by ignoring data from the Total Diet Study samples and its own analyses of that data

102. In denying the Perchlorate Petition and reaffirming the 2005 TOR Exemption approval, FDA entirely ignored its own study and analyses

demonstrating dramatically increased levels of perchlorate contamination in the diet following that TOR Exemption approval.

103. That information showed that the assumptions and models underlying FDA's analyses were wrong, and that perchlorate is entering the food supply at much higher levels than FDA anticipated. But FDA nevertheless relied on those flawed assumptions to deny the Perchlorate Petition.

104. FDA thus "entirely failed to consider an important aspect of the problem," and has "offered an explanation for its decision that runs counter to the evidence before the agency." *State Farm*, 463 U.S. at 43.

105. The Petition Denial was therefore "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

106. FDA's denial of the Perchlorate Petition has harmed and continues to harm Plaintiffs' members.

SECOND CLAIM FOR RELIEF:
FDA violated the APA by failing to account for foods contacting multiple perchlorate-containing food-contact articles

107. FDA entirely ignored the possibility that foods might contact multiple perchlorate-containing food-contact articles.

108. By ignoring the likelihood of multiple exposures, FDA's analysis underestimated the rate at which perchlorate in food packaging and other food-contact articles is likely to contaminate the food supply.

109. FDA thus "entirely failed to consider an important aspect of the problem." *State Farm*, 463 U.S. at 43.

110. The Petition Denial was therefore "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

111. FDA's denial of the Perchlorate Petition has harmed and continues to harm Plaintiffs' members.

THIRD CLAIM FOR RELIEF:
FDA violated the Food Act and the APA by failing to consider the cumulative effects of perchlorate in the diet

112. FDA's Petition Denial failed to consider "the cumulative effect" of perchlorate and related substances in the diet, in violation of 21 U.S.C. § 348(c)(5)(B).

113. Because FDA did not consider the cumulative effect of perchlorate contamination authorized by the TOR Exemption in combination with perchlorate contamination from other sources and contamination from pharmacologically related substances, FDA could not carry out its statutory responsibility to determine whether perchlorate use is "safe." *Id.* § 348(c)(5).

114. FDA thus "entirely failed to consider an important aspect of the problem," *State Farm*, 463 U.S. at 43, and acted contrary to the Food Act's requirements.

115. The Petition Denial was therefore "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

116. FDA's denial of the Perchlorate Petition has harmed and continues to harm Plaintiffs' members.

REQUEST FOR RELIEF

Plaintiffs respectfully request that this Court enter judgment against FDA as follows:

A. Declaring FDA's Petition Denial arbitrary, capricious, and not in accordance with the Food Act;

B. Vacating FDA's Petition Denial and remanding to the agency for further consideration and explanation promptly following this Court's decision; and

C. Granting such other relief as the Court deems just and proper.

Respectfully submitted,

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