

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

CENTER FOR FOOD SAFETY, BREAST)
CANCER PREVENTION PARTNERS,)
CENTER FOR SCIENCE IN THE PUBLIC)
INTEREST, ENVIRONMENTAL)
DEFENSE FUND, and)
ENVIRONMENTAL WORKING GROUP,)

Plaintiffs,)

v.)

TOM PRICE, SECRETARY,)
DEPARTMENT OF HEALTH AND)
HUMAN SERVICES; SCOTT GOTTLIEB,)
COMMISSIONER, UNITED STATES)
FOOD AND DRUG ADMINISTRATION;)
and UNITED STATES FOOD AND DRUG)
ADMINISTRATION,)

Defendants.)

) Case No.

) **COMPLAINT FOR DECLARATORY
AND INJUNCTIVE RELIEF**

) Administrative Procedure Act Case

I. INTRODUCTION

1. Plaintiffs Center for Food Safety, Breast Cancer Prevention Partners, Center for Science in the Public Interest, Environmental Defense Fund, and Environmental Working Group (“Plaintiffs”) seek declaratory and injunctive relief with respect to a final rule promulgated by the United States Food and Drug Administration (“FDA”) entitled “Substances Generally Recognized as Safe,” 81 Fed. Reg. 54,960 (Aug. 17, 2016) (“final rule” or “GRAS Rule”). The GRAS Rule allows potentially unsafe food additives to be used in the food supply (human and animal) without FDA review, approval, oversight, or knowledge, in violation of the Federal Food, Drug, and Cosmetic Act (“FDCA” or “the Act”), 21 U.S.C. §§ 342(a), 348; the

Administrative Procedure Act (“APA”), 5 U.S.C. § 701 *et seq*; and the U.S. Constitution.

2. The FDCA requires FDA to confirm the safety of a substance before it can be introduced into the food supply. One element of determining safety is considering the “probable consumption” of a substance, and its “cumulative effect” on health, taking exposure to similar chemical substances into account. 21 U.S.C. § 348(c)(5).

3. The GRAS Rule allows FDA to abdicate its core duty under the FDCA: to be responsible for the safety of the food supply. Under the procedures and criteria laid out in the GRAS Rule, manufacturers of substances used in processed food can self-certify—without notice to FDA or the public, and in furtherance of their own financial interests—that a use of a substance is “generally recognized as safe,” or GRAS.

4. Under the FDCA, a GRAS substance is not a “food additive.” Therefore, GRAS substances are not subject to the premarket safety review mandated for food additives.

5. Under the GRAS Rule, and in contravention of the FDCA, a manufacturer may self-certify a use of a substance as GRAS without FDA approval or knowledge, thereby bypassing the rigorous premarket review process for food additives.

6. The GRAS Rule does not require a manufacturer to notify FDA about any self-certified GRAS determinations, or to keep records documenting or explaining the basis of GRAS determinations. As a result, the GRAS Rule allows GRAS determinations and the use of GRAS substances in the food supply to remain *entirely secret from FDA and the public*.

7. Taken together, self-certification, lack of mandatory notice, and the absence of recordkeeping requirements result in a secret GRAS system: a regulatory scheme in which potentially unsafe chemical substances can be added to food based on conclusions by self-interested food and chemical manufacturers that their substances are “GRAS” without

FDA's oversight or knowledge. This secret GRAS system deprives FDA of the ability to verify that a use of a substance is truly "generally recognized as safe" within the meaning of the FDCA, despite the requirement that FDA oversee and be accountable for the "general recognition of safety" determination, and, more generally, ensure the safety of the food supply.

8. Further, as a result of the secret GRAS system, neither FDA, nor the public, nor other food and chemical manufacturers know, or could know, the identity of all chemical substances added to food—making it impossible for FDA, the public, and other food and chemical manufacturers to consider the cumulative effect of any new chemical substance on human health, as required by the FDCA.

9. As a separate matter, the criteria in the GRAS Rule for determining whether a use of a substance may be classified as GRAS are contrary to the FDCA itself. For example, the GRAS Rule states that uses may be self-certified as GRAS based on unpublished information corroborated by unpublished information. This violates the FDCA because there cannot be "general recognition" of safety in the absence of publicly available safety data.

10. In addition, entirely novel chemical substances and uses, including those made using nanotechnology or other novel manufacturing methods, can also be self-certified by manufacturers as GRAS and added to food without FDA knowledge, safety review, approval, or oversight. This violates the FDCA because a *novel* substance, by definition, has not been in existence long enough for its safety to have been studied by "experts qualified by scientific training and experience" and for there to be a general recognition of safety. 21 U.S.C. § 321(s).

11. Although the FDCA categorically excludes carcinogenic chemical substances from being approved as food additives, the GRAS Rule does not categorically prohibit manufacturers from self-certifying a use of a carcinogen as GRAS.

12. As a result of the secret GRAS system, organizations such as Plaintiffs, whose missions include monitoring the safety of food and providing information to their members and the public at large about food safety, nutrition, and health, are impaired in fulfilling their missions.

13. As a result of both the secret GRAS system and inadequate GRAS eligibility criteria, consumers (including members and supporters of Plaintiffs) are exposed to potentially dangerous chemical substances that FDA has not evaluated for safety, without any means to protect themselves or make informed choices. Some of the chemical substances that manufacturers have self-certified as GRAS present serious health risks.

14. Plaintiffs seek a declaratory judgment that FDA's final GRAS Rule violates fundamental principles of separation of powers, exceeds FDA's statutory authority, is not in accordance with law, is arbitrary and capricious, and is an abuse of discretion. Plaintiffs also request equitable relief vacating the unlawful GRAS Rule, remanding the matter to FDA to reissue a rule that is in accordance with the FDCA, and other relief this Court deems appropriate.

II. JURISDICTION AND VENUE

15. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331 (federal question) and 28 U.S.C. § 1346 (United States as defendant).

16. The relief requested is specifically authorized pursuant to 28 U.S.C. § 1651 (writs) and 28 U.S.C. §§ 2201-02 (declaratory relief). An actual controversy exists between the parties within the meaning of 28 U.S.C. § 2201 (declaratory judgments).

17. Plaintiffs have a right to bring this action pursuant to the Administrative Procedure Act, 5 U.S.C. § 702.

18. Venue properly lies in this Court pursuant to 28 U.S.C. § 1391(e) because

plaintiff Environmental Defense Fund resides in this district.

III. PARTIES

A. Plaintiffs

19. Plaintiff Breast Cancer Prevention Partners (“BCPP”) is a nonprofit organization headquartered in California that works to prevent breast cancer by eliminating exposure to toxic chemicals linked to the disease. BCPP has 65,000 supporters across the country. BCPP translates the growing body of scientific evidence linking breast cancer and environmental exposures, including from food additives, into public education and advocacy campaigns that protect public health and reduce breast cancer risk. BCPP undertakes food safety campaigns aimed to educate the public, participates in petitions to FDA, and lobbies for better legislation on food safety.

20. BCPP is currently and will continue to be hindered in carrying out its mission as a result of the secret GRAS system. As a result of the GRAS Rule, BCPP has diverted its resources to efforts that would otherwise have been unnecessary; BCPP has had to shift staff time from other efforts to protect its supporters and the public from toxic threats to fighting the illegal secret GRAS system and getting basic information about toxic substances in food. BCPP staff has spent time educating their constituency about the problems with the GRAS program by writing and calling companies to inquire about GRAS chemicals, and by publishing information about the secret GRAS system. Due to the secret GRAS system, BCPP cannot obtain access to safety information that it would otherwise be entitled to obtain about food ingredients through the premarket food additive review process, and about the identity and use of substances self-certified as GRAS through what should be a public GRAS process. Given that ingredient panels do not disclose the specific identity of all substances added to food—*e.g.*, the broad array

of ingredients characterized as “artificial flavors” and “natural flavors”—the secret GRAS system renders BCPP unable to identify all chemicals added to food and therefore unable to fulfill its mission of informing its supporters, the public, and the government about food safety issues associated with GRAS chemical substances or cumulative effects of food additives and GRAS chemical substances. Hereafter, references to BCPP are to the organization and its members.

21. Plaintiff Center for Food Safety (“CFS”) is a national nonprofit organization that has over 800,000 members nationwide and is headquartered in the District of Columbia. A cornerstone of CFS’s mission is protecting the public’s right to know how its food is produced. Through the dissemination of information addressing food technologies, such as nanotechnology, and chemicals used in food production, and their actual and potential harms, CFS encourages public involvement and governmental oversight of food safety issues. CFS members affiliate with CFS in order to guide and express their views on the issues on which CFS works; CFS, in turn, actively monitors regulatory and legislative developments that affect its central mission, and responds when necessary to protect the collective interests of its members, as in this litigation. CFS has active campaigns dedicated to preventing potentially harmful and untested chemical substances from entering our food supply. CFS, alone and in coalition with other groups, regularly submits petitions and comments to FDA requesting that it take protective actions with regard to harmful food additives. CFS has advocated for stronger regulation of food ingredients to FDA since FDA published its initial proposal for the GRAS Rule, and successfully brought suit to force FDA to finalize the GRAS Rule. *See* Consent Decree, ECF No. 15, *Ctr. for Food Safety v. Burwell*, No. 1:14-cv-00267-RC (D.D.C. Oct. 20, 2014).

22. CFS is currently and will continue to be hindered in carrying out its mission as a

result of the secret GRAS system. As a result of the GRAS Rule, CFS has diverted its resources to efforts that would otherwise have been unnecessary; CFS has had to shift staff time from other efforts to protect its supporters, the public, and the environment from toxic threats in food production to advocacy and raising public awareness about the inadequacies of the secret GRAS system and the resultant presence of secret GRAS ingredients in foods. CFS staff also monitor the safety of food ingredients and maintain a database of food products that use unapproved food technologies, including nano-scale ingredients that have been self-certified by industry as GRAS and used in foods without FDA's knowledge. Due to the secret GRAS system, CFS and its members cannot obtain access to safety information that they would otherwise be entitled to obtain about food ingredients through the premarket food additive review process, and about the identity and use of substances self-certified as GRAS through what should be a public GRAS process. Given that ingredient panels do not disclose the specific identity of all substances added to food—*e.g.*, the broad array of ingredients characterized as “artificial flavors” and “natural flavors”—the secret GRAS system renders CFS unable to fulfill its mission of informing its members, the public, and the government about food safety issues associated with GRAS chemical substances or cumulative effects of food additives and GRAS chemical substances; it is also hindered in its ability to protect its members from and advocate against harmful food additives and food technologies. CFS's members have purchased or consumed chemical substances that may pose serious risks to human health and are approved through the secret GRAS system. Therefore, CFS members are being, and will be, adversely affected by potentially unsafe chemical substances added to food. Hereafter, references to CFS are to the organization and its members.

23. Plaintiff the Center for Science in the Public Interest (“CSPI”) is a nonprofit organization headquartered in the District of Columbia that advocates for and educates consumers on issues of food safety, nutrition, and transparent advertising. A core part of CSPI’s mission is to provide consumers with current, useful information about their health and well-being. CSPI publishes the Nutrition Action Healthletter (“NAH”), which provides science-based advice on health and nutrition to approximately one million readers. Among CSPI’s principal goals is to provide objective information about food safety before regulatory, judicial, and legislative bodies. CSPI regularly advocates for greater transparency, disclosure, and safety of food ingredients and regularly submits petitions and comments to FDA requesting that it take protective actions with regard to harmful food additives.

24. CSPI is currently and will continue to be hindered in carrying out its mission as a result of the secret GRAS system. As a result of the GRAS Rule, CSPI has diverted its resources to efforts that would otherwise have been unnecessary; CSPI has had to shift staff time from other efforts to provide consumers and others with specific useful information about food and food ingredients to advocacy and raising public awareness about the inadequacies of the secret GRAS system. CSPI also spends staff time monitoring the safety of food ingredients and maintains databases that include information about the safety of GRAS chemical substances and adverse reactions to GRAS substances. Due to the secret GRAS system, CSPI cannot obtain safety information that it would otherwise be entitled to obtain about food ingredients through the premarket food additive review process, and about the identity and use of substances self-certified as GRAS through what should be a public GRAS process. Given that ingredient panels do not disclose the specific identity of all substances added to food—*e.g.*, the broad array of ingredients characterized as “artificial flavors” and “natural flavors”—the secret GRAS

system renders CSPI unable to identify all chemicals added to food and therefore unable to fulfill its mission of informing the public and the government about food safety issues associated with GRAS substances or cumulative effects of food additives and GRAS substances.

25. Plaintiff the Environmental Defense Fund (“EDF”) is a national nonprofit membership organization incorporated under the laws of the State of New York, with an office in New York, New York. EDF currently has over 385,000 members in the United States, residing in every state. A core part of EDF’s mission is to use science, economics, and law to protect human health from harmful chemicals. To accomplish this goal, EDF disseminates to government agencies, legislatures, its members, and the general public informational materials addressing food safety. EDF members affiliate with EDF in order to guide and express their views on the issues on which EDF works; EDF, in turn, actively monitors regulatory and legislative developments that impact its central mission, and responds when necessary to protect the collective interests of its members, as in this litigation.

26. EDF is currently and will continue to be hindered in carrying out its mission as a result of the secret GRAS system. As a result of the GRAS Rule, EDF has diverted resources to efforts that would otherwise have been unnecessary; EDF has had to shift staff time from other efforts to protect human health from harmful chemicals to attempting to monitor, research, and compile information on secretly affirmed GRAS chemical substances. EDF has also paid for access to resources that aid it in researching secret GRAS chemical substances. Due to the secret GRAS system, EDF and its members cannot obtain safety information that they would otherwise be entitled to obtain about food ingredients through the premarket food additive review process, and about the identity and use of substances self-certified as GRAS through what should be a public GRAS process. Given that ingredient panels do not disclose the specific identity of all

substances added to food—*e.g.*, the broad array of ingredients characterized as “artificial flavors” and “natural flavors”—the secret GRAS system renders EDF unable to identify all chemicals added to food and therefore unable to fulfill its mission of informing its members, the public, and the government about food safety issues associated with GRAS chemical substances or cumulative effects of food additives and GRAS chemical substances. In addition, EDF’s members have purchased or consumed chemical substances that may pose serious risks to human health and which have not been subjected to FDA review due to the secret GRAS system. Therefore, EDF members are being, and will be, adversely affected by potentially unsafe chemical substances added to food. Hereafter, references to EDF are to the organization and its members.

27. Plaintiff Environmental Working Group (“EWG”) is a nonprofit research and advocacy organization dedicated to empowering people to live healthier lives in a healthier environment through its educational reports, online guides, mobile apps, and related advocacy campaigns. EWG is incorporated and headquartered in the District of Columbia. EWG helps individuals reduce their exposures to harmful and potentially harmful chemical substances, including those found in food, through its Food Scores Database, Healthy Living mobile application, and educational reports. EWG also advocates for reform of federal regulation of chemical substances added to food, in order to give the public greater assurance that the food they eat does not contain ingredients that may prove detrimental their health. EWG provides the public with information about how to reduce exposure to potentially hazardous chemicals. EWG scientists have a history of researching and providing information about chemical substances that are considered GRAS.

28. EWG is currently and will continue to be hindered in carrying out its mission as a

result of the GRAS rule's optional notification system by being denied access to information that it would otherwise be able to obtain from FDA about food additives and GRAS substances. EWG's public educational resources, such as its food database, Food Scores, and its report "Dirty Dozen Food Additives List" are made less effective because EWG cannot obtain complete information about food additives as a result of the secret GRAS system. EWG has diverted resources to efforts that would otherwise have been unnecessary; EWG has had to shift staff time from other efforts to inform the public because it must spend additional time and resources merely to gather the basic data for its reports. Due to the secret GRAS system, EWG cannot obtain safety information that it would otherwise be entitled to obtain about food ingredients through the premarket food additive review process, and about the identity and use of substances self-certified as GRAS through what should be a public GRAS process. Given that ingredient panels do not disclose the specific identity of all substances added to food—*e.g.*, the broad array of ingredients characterized as "artificial flavors" and "natural flavors"—the secret GRAS system renders EWG unable to identify all chemicals added to food and therefore unable to fulfill its mission of informing the public and the government about food safety issues associated with GRAS chemical substances or cumulative effects of food additives and GRAS chemical substances.

B. Defendants

29. Defendant Tom Price is the Secretary of the United States Department of Health and Human Services, and is being sued in his official capacity.

30. Defendant Scott Gottlieb is the Commissioner of FDA, and is being sued in his official capacity. As Commissioner, Gottlieb has the ultimate responsibility for FDA's activities and policies.

31. Defendant FDA is an agency of the United States within the U.S. Department of Health and Human Services (“HHS”). The Secretary of HHS has delegated to FDA the authority to implement and administer the implement FDCA, and in that capacity is responsible for issuing the GRAS Rule.

32. Defendants Price, Gottlieb and FDA are collectively referred to as “FDA” or “Defendants.”

IV. STATUTORY BACKGROUND

A. Protections Against Unsafe Food Additives

33. The FDCA requires FDA to “protect the public health by ensuring that . . . foods are safe, wholesome, sanitary, and properly labeled[.]” 21 U.S.C. § 393(b).

34. In 1958, Congress enacted the Food Additives Amendment to the FDCA in response to concern among the public, lawmakers, and leading scientists that the food industry’s increasing use of untested chemical additives in food, and the lack of information about the possible chronic risks posed by such chemicals, posed a health risk to consumers.

35. The express purpose of the Food Additives Amendment is “to prohibit the use in food of additives which have not been adequately tested to establish their safety.” Food Additives Amendment of 1958, Pub. L. No. 85-929, 72 Stat. 1784.

36. Toward this end, the Food Additives Amendment mandates that any “food additive” must go through a rigorous approval process. Under this process, the burden is on the manufacturer to prove the safety of the use of the substance. FDA must review and approve the proposed use before the additive can be used in food. *See* 21 U.S.C. § 348.

37. Under the FDCA, it is the conditions of use of a substance, rather than the substance itself, that is eligible for GRAS status. Thus, the same substance will need a new

determination—either a food additive determination or a GRAS determination—for each new use. *See id.*

38. Under the Food Additives Amendment, a food additive is “deemed to be unsafe” with respect to any use “unless it and its use . . . are in conformity with[] a regulation prescribing conditions under which the additive may be safely used.” 21 U.S.C. § 348(a). Investigational use by qualified experts may also be permitted where allowed by regulation and consistent with public health. *Id.* § 348(j).

39. The FDCA establishes a process for manufacturers to petition FDA to issue a regulation prescribing conditions under which a food additive may be safely used. *Id.* § 348(b). FDA may not issue such a regulation if “a fair evaluation of the data before the Secretary fails to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe[.]” *Id.* § 348(c)(3).

40. The FDCA states that the term “safe” “has reference to the health of man or animal.” 21 U.S.C. § 321(u). While the Food Additives Amendment does not further define “safe,” both the House and Senate reports on the Amendment state that “safety requires proof of a reasonable certainty that no harm will result from the proposed use of an additive.” H.R. Rep. No. 85-2284, at 4 (1958); S. Rep. No. 85-2422, at 6 (1958), *as reprinted in* 1958 U.S.C.C.A.N. 5300, 5305.

41. The Food Additives Amendment sets forth factors that FDA must consider in assessing an additive’s safety. These considerations include “the probable consumption of the additive and of any substance formed in or on food because of the use of the additive,” and “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).

42. To determine the probable consumption of a chemical substance and cumulative effect of a proposed food additive in combination with already approved “chemically or pharmacologically related substances,” as the FDCA mandates, FDA must be aware of all chemical substances added to food and the amounts in which they are used. *Id.*

43. Explicit under the Food Additives Amendment is a role for the public and, where appropriate, the judiciary, in approval of food additives. Under the Food Additives Amendment: (a) FDA must publish notice of a proposed food additive regulation within 30 days of a petition being filed, *id.* § 348(b)(5); (b) FDA must make a final decision within 180 days of the petition filing, *id.* § 348(c); (c) members of the public who would be adversely affected by FDA’s final decision may file objections, *id.* § 348(f)(1); (d) adversely affected individuals may also request a public hearing upon their objections, *id.*; (e) if requested, FDA must hold a public hearing to receive evidence relevant to the objections, *id.*; and (f) any FDA regulation approving use of a food additive is subject to judicial review, *id.* § 348(g).

44. Only after a food additive manufacturer petitions FDA to approve a use, and FDA reaches a substantive finding of safety, may the additive be used in the food supply for that specified use in specified amounts.

B. Chemical Substances That Are “Generally Recognized as Safe”

45. The Food Additives Amendment mandates that any “food additive” must go through the rigorous food additive approval process. It defines a food additive as

any chemical 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 chemical substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), *if such chemical substance is not*

generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a chemical substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use.

21 U.S.C. § 321(s) (emphasis added).

46. Under this definition, uses of chemical substances that are “generally recognized as safe” are not considered to be “food additives” for such uses. Since they are not “food additives,” GRAS uses of chemical substances are exempt from the premarket review established under the Food Additives Amendment, and may be marketed without FDA review, approval, oversight, or knowledge.

47. By declaring the use of a substance to be “GRAS,” a manufacturer bypasses the lengthy food additive approval process, including public participation and the option of judicial review, described in paragraph 43, *supra*.

48. The “generally recognized” clause was copied verbatim from the provisions already in force under the original FDCA regulating new drugs. Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040, 1041-42 (1938) (“The term “new drug” means – (1) Any drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of drugs, as safe for use....”).

C. The GRAS Rule and its History

49. Under the regulations in effect prior to the 1997 proposed GRAS Rule, food additive manufacturers could file a petition asking FDA to affirm the GRAS status of a particular use of a chemical substance, thereby confirming that the chemical substance was not a food additive under the FDCA. In seeking an affirmation, the petitioner had to provide FDA with all

backup information demonstrating general scientific agreement that the proposed use was safe. Within thirty days of receiving an affirmation petition, FDA was required to publish a notice of filing in the Federal Register and allow a 60-day comment period. After considering the petition, scientific data, and comments, FDA could either publish an order adding the chemical substance to the list of affirmed GRAS chemical substances or publish a ruling that the chemical substance is not GRAS and is therefore considered a food additive. The explanation had to be published in the Federal Register.

50. In April 1997 FDA proposed the GRAS Rule, which weakened the prior regulatory scheme by repealing manufacturers' option of filing a GRAS affirmation petition and seeking FDA approval of their GRAS determinations. Under the proposed GRAS Rule, manufacturers independently made GRAS determinations and FDA did not review, affirm, or reject those determinations. Food additive manufacturers merely had the *option* of notifying FDA that *they* have concluded that a use of a chemical substance is GRAS. With the proposed GRAS Rule, FDA also weakened the substantive criteria by which a manufacturer determines whether the use of one of its chemical substances is GRAS. *See Substances Generally Recognized as Safe*, 62 Fed. Reg. 18,938 (Apr. 17, 1997) (proposed rule).

51. When it published the proposed rule, FDA announced the food industry should begin using the optional notification process rather than continue to petition FDA for affirmation of a use's GRAS status. *See id.* FDA operated under this proposed rule for 19 years before publishing the final rule at issue here.

52. FDA took no further action regarding the GRAS system, and did not take any action to finalize the proposed GRAS rule until it was required to do so by court order in a case brought by plaintiff CFS. *See Consent Decree*, ECF No. 15, *Ctr. for Food Safety v. Burwell*, No.

1:14-cv-00267-RC (D.D.C. Oct. 20, 2014).

53. On August 17, 2016, FDA published the final GRAS Rule, codifying its practice of allowing self-certified GRAS chemical substances to be added to food without FDA review, approval, oversight, or knowledge, and without public participation. Substances Generally Recognized as Safe, 81 Fed. Reg. 54,960 (Aug. 17, 2016). Thus, although the final rule was promulgated only recently, it is very similar to the process that has been in effect for nearly 20 years.

D. The GRAS Determination Process Under the GRAS Rule

54. Despite FDA's obligation to oversee the safety of food, the GRAS Rule allows manufacturers to certify use of a substance as GRAS without letting FDA know. Although manufacturers can *choose* to submit a GRAS notice to FDA, they are under no obligation to do so by the GRAS Rule. 21 C.F.R. § 170.205 (“Any person *may* notify FDA of a view that a substance is not subject to the premarket approval requirements of [the FDCA].”) (emphasis added).

55. Much of the GRAS Rule is devoted to the process manufacturers are to use *if* they choose to submit a GRAS notice to FDA.

56. The Rule defines a GRAS notice as a “submission that informs [FDA] of your”—meaning the manufacturer's—“view that a substance is not subject to the premarket approval requirements of the [FDCA] based on *your conclusion* that the substance is GRAS under the conditions of its intended use in accordance with § 170.30.” 21 C.F.R. § 170.203 (emphasis added).

57. The GRAS Rule makes clear that submitting a GRAS notice is optional: “Any person *may* notify FDA of a view that a substance is not subject to the premarket approval

requirements of [the FDCA].” *Id.* § 170.205 (emphasis added).

58. When a manufacturer chooses to submit a GRAS notice, the Rule provides that FDA will respond by letter indicating whether it has questions about the manufacturer’s conclusion that its own chemical substance is GRAS for a particular use. 21 C.F.R. § 170.265. However, even when FDA does not question a manufacturer’s conclusion, it is not affirmatively agreeing that the chemical substance is safe; it is merely not disagreeing with the manufacturer’s conclusion about its own product. *See* 81 Fed. Reg. at 55,014-15.

59. If FDA notifies a food additive manufacturer that its GRAS notice is insufficient, or raises safety questions, the manufacturer can simply withdraw the notice and proceed to secretly self-certify use of the chemical substance as GRAS without FDA’s review, approval, oversight, or knowledge. The record includes evidence of such instances, as discussed below.

60. Nothing in the GRAS Rule prevents a manufacturer from marketing a chemical substance before submitting a GRAS notice to FDA, during FDA’s evaluation of a GRAS notice, or, indeed, without ever submitting a GRAS notice to FDA.

E. The Criteria for GRAS Determinations Under the GRAS Rule

61. Under the Food Additives Amendment, for chemical substances used in food prior to January 1, 1958, the GRAS determination may be made through either scientific procedures or experience based on common use in food prior to passage of the law. The determination of GRAS status through common use prior to 1958 is not at issue here. For substances developed or newly used in food since 1958, a GRAS determination must be made based on “scientific procedures.” 21 U.S.C. § 321(s).

62. Under the Food Additives Amendment, use of a chemical substance is GRAS based on scientific procedures if it is:

- “*generally recognized*;
- among *experts* qualified by scientific training and experience to evaluate its safety;
- as having been adequately shown through *scientific procedures* ...;
- to be *safe* under the conditions of its intended use.”

Id. (emphasis and bullets added).

63. Under the FDCA, safety requires “proof of a reasonable certainty that no harm will result from the proposed use of an additive.” *See* H.R. Rep. No. 85-2284, at 4 (1958); S. Rep. No. 85-2422, at 6 (1958), *as reprinted in* 1958 U.S.C.C.A.N. 5300, 5305. Under the GRAS Rule, “general recognition of safety” requires “*common knowledge* throughout the scientific community knowledgeable about the safety of substance directly or indirectly added to food” and requires the “same quality and quantity of evidence as is required to obtain approval of a food additive.” 21 C.F.R. § 170.30(a), (b) (emphasis added).

64. Unlike the Food Additives Amendment, which requires that GRAS determinations be made by “experts qualified by scientific training and experience to evaluate [food additive] safety,” 21 U.S.C. § 321(s), the GRAS Rule requires GRAS determinations to be based on “common knowledge throughout the scientific community knowledgeable about the safety of chemical substances ... added to food.” 21 C.F.R. § 170.30(a).

65. Unlike the Food Additives Amendment, which requires proposed GRAS substances to be “adequately shown” through scientific procedures to be safe, 21 U.S.C. § 321(s), the GRAS Rule explains that GRAS determinations based on “scientific procedures” shall be based upon “the application of generally available and accepted scientific data, information, or methods, which *ordinarily* are published, as well as the application of scientific

principles, and may be corroborated by the application of *unpublished scientific data, information, or methods.*” 21 C.F.R. § 170.30(b) (emphasis added). The GRAS Rule further defines the term “scientific procedures” as “the application of scientific data . . . , information and methods, whether published *or unpublished*, as well as the application of scientific principles, appropriate to establish the safety of a chemical substance under the conditions of its intended use.” *Id.* § 170.3(h) (emphasis added).

66. The GRAS Rule thus allows a manufacturer’s determination that safety is “generally recognized” to be based on unpublished information corroborated by unpublished information.

V. STATEMENT OF FACTS

67. Concerns about the secret GRAS system have been evident since FDA began implementing it in 1997. However, because the hallmark of the GRAS Rule is *secret* decision-making, Plaintiffs have been deprived of full information about the consequences of implementing the GRAS Rule.

68. Despite the secrecy, Plaintiffs are aware that thousands of GRAS chemical substances are used extensively in processed food, many of which have not gone through a public, unbiased safety review.

69. In 2010, the Government Accountability Office (“GAO”) issued a sharply critical report, *FDA Should Strengthen Its Oversight of Food Ingredients Determined to Be Generally Recognized as Safe*, GAO-10-246 (“GAO Report”). The GAO Report noted that since 1997, most GRAS determinations have been premised on the “common knowledge” of panels of industry experts, without any assurance that the panelists are independent and free of conflicts. The GAO report indicated that the GRAS Rule is especially concerning in the context of

nanotechnology, because companies may conclude that engineered nanomaterials are GRAS without informing FDA. The GAO Report is in the GRAS rulemaking docket.

70. In 2013, the Journal of the American Medical Association (“JAMA”) published Thomas G. Neltner et al., *Conflicts of Interest in Approvals of Additives to Food Determined to Be Generally Recognized as Safe*, 173 JAMA Intern. Med. 2032, 2035 (2013) (“JAMA Conflict of Interest Study”), which outlines conflicts of interest in GRAS determinations from 1997, when the “interim” notification process went into effect, through 2012. Out of 451 GRAS notifications submitted to FDA, the authors found that 22.4% of the safety assessments were made by an employee of an additive manufacturer, 13.3% by an employee of a consulting firm selected by the manufacturer, and 64.3% by an expert panel selected by either a consulting firm or the manufacturer. The study also revealed that manufacturers repeatedly hired the same “experts” to make their GRAS determinations, with one individual serving on more than 44% of the studied GRAS determination panels, and more than 75% of panels including at least one of ten “experts” most frequently chosen to make GRAS determinations. None of the determinations were made by panels selected by independent third parties. This means that each manufacturer compensated “experts”—either directly or through a consulting firm—to evaluate the safety of their own products. The JAMA Conflict of Interest Study is in the GRAS rulemaking docket.

71. In 2013, a Pew Charitable Trusts report entitled “Fixing the Oversight of Chemicals Added to Our Food” (“Pew Report”) found that over the past decade, *almost all* new chemicals added directly to food have been through the GRAS process, rather than the statutory food additive petition process. According to the Pew Report, of the roughly 10,000 additives currently used in food, more than 3,000 have never been scrutinized for safety by FDA. For an

estimated 1,000 of these chemical substances, safety decisions were made by the food industry without any notice to FDA. The Pew Report is in the GRAS rulemaking docket.

72. Almost 60% of the calories in a typical American diet are comprised of ultra-processed foods that contain many food additives.¹ As a result, the vast majority of American consumers, including members of Plaintiff organizations, are exposed to chemical substances in food that have not gone through premarket safety review because their manufacturers deemed their use to be GRAS.

A. Chemical Substances of Concern Approved as GRAS

73. In 2014, the Natural Resources Defense Council issued a report (“GRASecret Report”), *Generally Recognized as Secret: Chemicals Added to Food in the United States*, based on its complex and expensive attempt to identify chemical additives that have been secretly self-certified as GRAS, after the manufacturers withdrew their GRAS notifications in response to FDA questions. The report necessarily omitted manufacturers who opted to bypass the notification process entirely.

74. The GRASecret Report sheds light on several GRAS chemical substances in use at the time it was released. The GRASecret Report shows that the secret GRAS system allows chemical substances of concern to be added to food without FDA review, approval, oversight, or knowledge.

75. The GRASecret Report authors identified more than 25 food products containing epigallocatechin-3-gallate (“EGCG”). A company submitted and withdrew GRAS notices for EGCG twice. The GRAS notices did not explain potentially dangerous interactions with

¹ See Eurídice Martínez Steele et al., *Ultra-processed foods and added sugars in the US diet: evidence from a nationally representative cross-sectional study*, 6 *BMJ Open* e009892 (2016), DOI: 10.1136/bmjopen-2015-009892.

sodium nitrite, a common preservative, or with acetaminophen, a common ingredient in over-the-counter painkillers. FDA identified red flags with respect to EGCG's safety, including evidence that it may cause leukemia in fetuses, and a study in rats showing that it affected the thyroid, testis, spleen, pituitary, liver, and gastrointestinal tract. Despite FDA's concerns, the manufacturer secretly self-certified EGCG as GRAS, and other companies still used EGCG in their products as of 2014.

76. The GRASecret Report also identified food products containing added Gamma-amino butyric acid ("GABA"), a neurotransmitter. The manufacturer of GABA submitted a GRAS notice to FDA, which relied on unpublished safety studies, and failed to consider existing exposures. FDA responded that cumulative consumer exposure to GABA, which included the proposed new uses and the GABA naturally present in other foods such as meats, would exceed the levels that the company considered to be safe. When FDA identified these concerns, the company withdrew its notice and secretly self-certified GABA as GRAS. The company told the authors of the GRASecret Report that it would not market the product for use in food without a final review from FDA, but the authors found GABA listed as an ingredient in bottled tea and nutrition bars, suggesting that other manufacturers were using the substance without notice to FDA.

77. The GRASecret Report found that theobromine was an ingredient in more than 20 food products, including isotonic waters, nutrition bars, and diet foods. The manufacturer of theobromine submitted a GRAS notice to FDA that did not provide explanations for various safety concerns raised by animal testing of theobromine, including testicular degeneration and delayed bone formation. FDA concluded that some consumers would ingest more than five times the safe level reported by the company's consultant. When FDA expressed concerns about

theobromine's safety, the manufacturer withdrew its notice and secretly self-certified theobromine as GRAS for use in bread, cereal, beverages, chewing gum, tea, soy milk, gelatin, candy, yogurt, and fruit smoothies.

78. Sweet lupin protein, fiber, and flour were declared GRAS by an Australian firm for use in baked goods, dairy products, gelatin, meats, and candy, despite concerns that the chemicals could cause potentially severe allergic reaction in people with peanut allergies. The manufacturer originally notified FDA of its GRAS determination, but then withdrew its notification after FDA noted that a warning label would be insufficient to alert consumers to the risk of an allergic reaction in people with peanut allergies. Despite FDA's concerns, sweet lupin is an ingredient in more than 20 food products, apparently based on a manufacturer's self-certification that the substance is GRAS. None of the food products that contain sweet lupin include a warning for those with peanut allergies.

B. Novel Chemical Substances Approved as GRAS

79. A novel group of chemical substances known as "taste modifiers" have been secretly self-certified as GRAS. These types of chemicals, 4-amino-5,6-dimethylthieno[2,3-d]pyrimidin-2(1H)-one & hydrochloride salt and 3-[(4-amino-2,2-dioxido-1H-2,1,3-benzothiadiazin-5-yl)oxy]-2,2-dimethyl-N-propylpropanamide, are lab-created to modify how humans perceive flavors. These chemicals are designated on food labels as simply "artificial flavors" or "flavorings," despite the manufacturer's acknowledgment that they do not have any taste of their own. Thus, consumers cannot detect their use in the food supply. In response to an inquiry by Plaintiff CSPI, FDA indicated that the manufacturer had not submitted any information on the chemical substances to FDA, and therefore FDA had not conducted any evaluation of the chemical substances.

80. Titanium Dioxide (TiO₂) nanoparticles appear in food products from their use as a flow and reflecting agent.² FDA approved bulk-scale TiO₂ as a color additive to whiten food; it has not approved nano-scale TiO₂ as a food or color additive, nor has it received notice of a GRAS determination, suggesting that it is being added to foods in a manner inconsistent with the law. Studies have shown associations between food-grade TiO₂ (in bulk- and nano-scale), and negative effects on both rat intestines³ and human nutrient absorption.⁴ Engineered nanomaterials are created through manipulation of particles at a molecular scale, which alters the physical properties of a substance without changing its chemical structure. Even when a substance such as TiO₂ is considered a safe additive at the bulk scale, it may have a unique effect on the human body at the nano scale. This is because nanomaterials can alter which toxic effects may occur, and can also affect bioavailability of a substance by altering absorption, metabolism, or excretion. Hence, FDA has recognized in a non-binding guidance document that evaluating the safety of a nano-scale version of a substance raises unique risks and methodological requirements, and therefore any uses of nanomaterials in food are ineligible for a GRAS designation.⁵ However, because the GRAS Rule permits manufacturers to self-certify

² See Alex Weir et al., *Titanium Dioxide Nanoparticles in Food and Personal Care Products*, 46 *Envtl. Sci. & Tech.* 2242 (2012), DOI: 10.1021/es204168d.

³ Sarah Bettini et al., *Food-grade TiO₂ impairs intestinal and systemic immune homeostasis, initiates preneoplastic lesions and promotes aberrant crypt development in the rat colon*, 7 *Scientific Rep.* 40373 (2017), DOI: 10.1038/srep40373.

⁴ Zhongyuan Guo et al., *Titanium dioxide nanoparticle ingestion alters nutrient absorption in an in vitro model of the small intestine*, 5 *NanoImpact* 70 (2017), DOI: 10.1016/j.impact.2017.01.002.

⁵ FDA, *Guidance for Industry: Assessing the Effects of Significant Manufacturing Process Changes, Including Emerging Technologies, on the Safety and Regulatory Status of Food Ingredients and Food Contact Substances, Including Food Ingredients that are Color Additives* 13-16 (June 2014), <https://www.fda.gov/downloads/Cosmetics/GuidanceRegulation/GuidanceDocuments/UCM300927.pdf>.

chemical substances as GRAS without notice to FDA, FDA cannot readily monitor if manufacturers are complying with the nonbinding guidance that precludes nanomaterials from being certified as GRAS—as is suggested from the fact that nano-scale TiO₂ is found in food products despite not having been approved by FDA.

C. FDA Criticism of the Secret GRAS System

81. In August 2014, FDA officials told the Washington Post that the agency “do[es] not know the volume of particular chemicals that are going into the food supply so [it] can diagnose trends,” and it “do[es] not know what is going on post-market.”⁶

82. In the same article, former Deputy FDA Commissioner for Foods Michael Taylor is quoted as saying that FDA “simply do[es] not have the information to vouch for the safety of many of these chemicals.” He further acknowledged, with regard to manufacturers’ ability to self-certify the GRAS status of their products:

This is the opposite of what the . . . law intended. . . . The law was meant to increase public scrutiny of additive safety by encouraging companies to publish their science in academic journals. . . . The assessments need to be based on publicly available information where there is agreement among scientists. It has got to be more than three employees in a room looking at information that is only available to them.

Id.

83. In 2016, former Commissioner David Kessler referred to the GRAS program as a “joke,” noting that the industry decides whether its own products are safe.⁷

⁶ Kimberly Kindy, *Food Additives on the Rise as FDA Scrutiny Wanes*, Washington Post, Aug. 17, 2014, https://www.washingtonpost.com/national/food-additives-on-the-rise-as-fda-scrutiny-wanes/2014/08/17/828e9bf8-1cb2-11e4-ab7b-696c295ddfd1_story.html.

⁷ The Aspen Inst., *Deep Dive: Six FDA Commissioners Take the Stage* [Transcript] 27 (June 25, 2016), <https://www.aspenideas.org/sites/default/files/transcripts/Deep-Dive-Six-FDA-Commissioners-Take-the-Stage.pdf>.

84. Even in the Federal Register notice for the GRAS Rule, FDA acknowledged significant weaknesses with the secret GRAS system that it was promulgating. FDA noted that: “When there are new uses of an added food substance without FDA’s premarket engagement, presumably because a manufacturer has concluded that such a use is GRAS, we [FDA] must react to the new uses after they emerge. In such cases, *it can be challenging for FDA to accurately assess consumption patterns and intake levels and to determine whether those new uses are safe and lawful in light of all the available safety data.*” 81 Fed. Reg. at 54,965 (emphasis added).

85. Despite this clear recognition of the inadequacies of the secret GRAS system, and FDA’s clear obligations under the FDCA, the final GRAS Rule does not enable FDA to fulfill its obligation to ensure the safety of the food supply.

VI. GENERAL ALLEGATIONS

86. The final GRAS Rule codifies a system under which manufacturers can add chemical substances to food without FDA knowledge, review, approval, or oversight, and without public participation. The GRAS Rule is unlawful and impermissible for several reasons.

A. The GRAS Rule Unlawfully Subdelegates Statutory Authority to Private Parties

87. The GRAS Rule does not require manufacturers to notify FDA of the use of chemical substances that manufacturers have self-certified to be GRAS.

88. Instead, manufacturers decide whether their own products are GRAS for particular uses, in which case the manufacturers can simply *opt out* of FDA’s premarket safety review without FDA knowledge, approval, or oversight.

89. As a result, FDA does not and cannot independently evaluate the safety of chemical substances that manufacturers self-certify as GRAS without notice to FDA, nor does or

can it determine whether use of a chemical substance is GRAS, before the chemical substance enters the market. The GRAS Rule removes the key and statutorily-required independent determination of whether a chemical substance is GRAS or subject to premarket review from FDA's control and places it within the purview of the industry that FDA is statutorily required to regulate.

90. In the GRAS Rule, FDA has sub-delegated to private, self-interested parties the authority given to it by Congress to "protect the public health by ensuring that . . . foods are safe." 21 U.S.C. § 393(b).

91. FDA's abdication of responsibility with regard to GRAS chemical substances prevents the Agency from carrying out its mandatory duty under the FDCA to protect the American food supply and public health from potentially unsafe food additives.

92. The GRAS Rule does not take into account that manufacturers have a financial incentive to self-certify substances as GRAS to avoid the lengthy and expensive food additive petition process.

93. Because FDA does not make an independent determination regarding whether use of a substance is GRAS, a manufacturer's self-determination that use of its own substance is GRAS is insulated from judicial review, denying Plaintiffs and their members a right to challenge in court whether a substance or use is in fact "GRAS."

B. The Secret GRAS System Is Contrary to the FDCA

94. The secret GRAS system makes it impossible for FDA to comply with its mandatory statutory duties, including enforcement duties, under the FDCA, and reflects an abdication of FDA's statutory duty to implement and enforce the Food Additives Amendment.

95. Ample evidence exists in the record before FDA demonstrating widespread industry abuse of the GRAS exemption.

96. The FDCA requires FDA to conduct a premarket safety review of all food additives—including proposed uses of GRAS substances, which are considered unapproved food additives unless determined to be GRAS—and lays out specific factors that the Agency must consider when approving the use of food additives. Two such factors are probable consumption of a food additive and the cumulative effects of the additive when combined with probable consumption of any other chemically and pharmacologically related substance(s). 21 U.S.C. § 348(c)(5).

97. Because the GRAS Rule requires the same quality of information to be submitted for GRAS substances as for food additives, 21 C.F.R. § 170.30(b), it likewise requires manufacturers making GRAS determinations to estimate and consider all dietary sources of exposure to a substance, including exposure to any chemically or pharmacologically related substances in the diet.

98. Because the GRAS Rule does not mandate notice to FDA of manufacturers' GRAS determinations, it is nearly impossible for manufacturers to know of and consider all other sources of dietary exposure to chemical substances that are chemically or pharmacologically related to their own.

99. This lack of information makes it nearly impossible for manufacturers to provide FDA with an accurate estimate of all dietary sources of exposure to their chemical substance.

100. This lack of information and the absence of a recordkeeping requirement also results in FDA lacking comprehensive data about actual use of substances declared to be GRAS, which would be needed to calculate or estimate dietary exposure.

101. Neither manufacturers nor FDA can conduct the cumulative exposure assessments needed to determine if a chemical substance is “safe” under the FDCA.

102. These flaws, inherent to the secret GRAS system, render it nearly impossible for manufacturers to comply with the GRAS Rule’s cumulative exposure requirement. They further render it impossible for FDA to gather and evaluate cumulative exposure data that are necessary to carry out its statutory duties, including enforcement of the FDCA.

103. The GAO Report found that the secret GRAS system makes it almost impossible for FDA to comply with its primary duties under the FDCA:

Once a GRAS chemical substance has entered the marketplace, FDA would find it difficult to identify that chemical substance as the potential source of a food safety problem, especially if FDA is unaware that the chemical substance has been determined to be GRAS. Food products may contain numerous ingredients, including GRAS chemical substances, making it difficult, if not impossible, for public health authorities to attribute a food safety problem to a specific GRAS chemical substance. Moreover, while FDA receives reports of adverse reactions to food, it is difficult to clearly identify any specific GRAS chemical substance as the likely cause of a foodborne illness from these reports.

GAO Report at 12.

104. As a result of the secret GRAS system, including the lack of mandated recordkeeping, FDA does not have the information it would need to police the border between GRAS substances and food additives. FDA has offered no explanation for how it intends to enforce the Food Additives Amendment in the absence of mandatory notice of manufacturers’ self-certified GRAS determinations, or mandatory recordkeeping for those determinations.

C. Criteria for GRAS Determinations Are Contrary to the FDCA

105. The criteria in the GRAS Rule for GRAS eligibility are contrary to, and inconsistent with, the FDCA.

106. The FDCA states that a chemical substance may be GRAS if it is “generally recognized, *among experts qualified by scientific training and experience to evaluate its safety*, as having been *adequately shown* through scientific procedures to be safe under the conditions of use.” 21 U.S.C. § 321(s) (emphasis added).

107. The GRAS Rule requires “general recognition” to be based on the views of “the scientific community knowledgeable about the safety of chemical substances . . . added to food.” 21 C.F.R. § 170.30(a). This “community” includes employees of the manufacturers, paid to sit on private GRAS determination panels. *See* JAMA Conflict of Interest Study at 2035. The GRAS Rule therefore allows secret GRAS determinations to be made by individuals whose employers will reap a financial benefit if uses of their substances are self-certified as GRAS, thereby avoiding the cumbersome food additive petition process.

108. The GRAS Rule also allows food manufacturers to “adequately show[]” that safety is “generally recognized” by means of unpublished scientific procedures, which can be corroborated with unpublished data, information, or methods—in other words, unpublished papers that are *not* publicly available, such as those written by food industry scientists and not subject to the peer review process.

109. The GRAS Rule allows GRAS determinations to be based on privately-held data and information, even if qualified experts do not have access to such data and information. This is not a permissible reading of the terms “generally recognized” and “adequately shown.”

110. Finally, the GRAS Rule allows manufacturers to self-certify totally novel chemical substances or uses as GRAS, even though, by definition, there cannot be “general recognition” of the safety of a substance or use for which the chemical structure, metabolism, health effects, and/or usage levels have never been described in the open scientific literature.

Consensus is impossible to achieve if a chemical's existence and use are unknown to the general scientific community (or the relevant segment of it) and to FDA.

111. None of the provisions of the GRAS Rule are severable from the rule as a whole.

D. Harm to Plaintiffs

112. Plaintiffs and their members have been and continue to be injured by the GRAS Rule and FDA's failure to collect basic information about chemical substances added to food.

113. Plaintiffs' organizational purposes are adversely affected by FDA's action, which prevents Plaintiffs from obtaining access to information about GRAS chemical substances that they would use to more effectively advocate for public health, food safety, and consumer rights, and from participating in the public process that is central to the food additive petition process. Furthermore, but for FDA's actions, Plaintiffs would not have to spend as much of their resources seeking basic information about GRAS chemical substances and their safety, and could direct these resources to other priorities.

114. The Court can craft equitable relief that will redress Plaintiffs' informational and organizational injuries.

115. Plaintiffs' members are injured because, among other things, the GRAS notification system has allowed potentially unsafe chemical substances into the market. Plaintiffs' members comprise thousands of individuals, many of whom regularly eat processed foods and are exposed to an increased risk of harm as a result of consuming chemical substances that manufacturers have privately determined to be GRAS without notifying FDA. Plaintiffs' members also lack access to information about GRAS chemical substances that would empower them to make informed food choices and notify FDA of potential problems.

116. At least some of the estimated thousand chemical substances that have been self-certified as GRAS without notice to FDA under the secret GRAS system should be considered food additives, because they are not “generally recognized as safe” within the meaning of the FDCA.

117. These “food additives-in-fact” that have been self-certified as GRAS should have undergone premarket safety review via the food additive petition process before they were added to food.

118. If the food additives-in-fact had gone through the food additive petition process before being added to food, which would have occurred but for the secret GRAS system that virtually invites abuse by the food industry, Plaintiffs and their members would have more information about the chemical substances added to their food because notice of the filing of food additive petitions must be published in the Federal Register, with detailed information available through the Freedom of Information Act. In addition, Plaintiffs and their members would have had the opportunity to provide comments, and/or request a hearing, on any food additive petitions seeking approval of food additives-in-fact that instead were self-certified as GRAS.

119. For these reasons, the secret GRAS system denies Plaintiffs and their members information to which they are legally entitled.

120. The secret GRAS system also denies Plaintiffs and their members the ability to participate in the FDCA-mandated comment period on food additive petitions.

121. These injuries are actual, concrete, ongoing, and particularized, and monetary damages cannot redress them. The requested relief will redress these injuries.

VII. CLAIMS FOR RELIEF

A. FIRST CLAIM FOR RELIEF: Unconstitutional Sub-Delegation of Statutory Authority

122. The secret GRAS system allows final decisions as to the safety and regulatory status of potential food additives to be made by private parties without FDA oversight or knowledge.

123. FDA has foreclosed from judicial review actions that it is statutorily required to carry out, undermining the constitutional balance between the federal branches. The system of separated powers and checks and balances established in the Constitution was regarded by the Framers as “a self-executing safeguard against the encroachment or aggrandizement of one branch at the expense of the other.” *Buckley v. Valeo*, 424 U.S. 1, 122 (1976).

124. The GRAS Rule violates the doctrine against sub-delegation and the separation of powers principle by placing agency authority in the hands of self-interested private entities without retaining oversight.

B. SECOND CLAIM FOR RELIEF: Agency Action Contrary to Constitutional Power in Violation of the APA

125. A reviewing court must hold unlawful and set aside agency action found to be “contrary to constitutional right, power, privilege or immunity.” 5 U.S.C. § 706(2)(B).

126. The secret GRAS system allows final decisions as to the safety and regulatory status of potential food additives to be made by private parties without FDA oversight or knowledge.

127. FDA has foreclosed from judicial review actions that it is statutorily required to carry out, undermining the constitutional balance between the federal branches in violation of Article I.

128. The GRAS Rule violates the doctrine against sub-delegation and the separation of powers principle by placing statutory authority in the hands of self-interested private entities without retaining oversight and foreclosing from judicial review actions that FDA is statutorily required to carry out.

C. THIRD CLAIM FOR RELIEF: Agency Action in Excess of Statutory Authority and Not in Accordance with the FDCA in Violation of the FDCA and APA

129. A reviewing court must hold unlawful and set aside agency action found to be “not in accordance with law,” or “in excess of statutory jurisdiction, authority, or limitations, or short of statutory right.” 5 U.S.C. § 706(2)(A), (C).

130. The GRAS Rule exceeds FDA’s authority, is not in accordance with the FDCA, and violates the APA insofar as:

- a. FDA sub-delegates authority to make GRAS determinations to private parties and does not retain the discretion to approve, disapprove, or modify those GRAS determinations thereby insulating the GRAS determinations from judicial review;
- b. FDA does not mandate notice of all GRAS conclusions, rendering it impossible to gather and evaluate cumulative exposure and effects data that are necessary to carry out its statutory duties, including enforcement of the statute;
- c. FDA does not mandate that records be kept documenting the basis for all self-certified GRAS conclusions, rendering it impossible for FDA to carry out its statutory duties, including enforcement of the statute;
- d. FDA’s criteria for GRAS classification are contrary to, and less protective than, the criteria in the FDCA; and

- e. FDA's criteria for GRAS classification do not reflect a permissible construction of the FDCA.

D. FOURTH CLAIM FOR RELIEF: Arbitrary and Capricious Agency Action in Violation of the APA

131. A reviewing court must hold unlawful and set aside agency action found to be arbitrary and capricious or an abuse of discretion. 5 U.S.C. § 706(2)(E).

132. The GRAS Rule is an arbitrary and capricious exercise of FDA's rulemaking authority in violation of the APA because:

- a. FDA does not retain the discretion to approve, disapprove, or modify the GRAS determinations made by private entities, thereby insulating GRAS determinations from judicial review;
- b. FDA does not mandate notice of all GRAS conclusions, rendering it impossible to gather and evaluate cumulative exposure and effects data that are necessary to carry out its statutory duties, including enforcement of the statute;
- c. FDA does not mandate that records be kept documenting the basis for all self-certified GRAS conclusions, rendering it impossible for FDA to carry out its statutory duties, including enforcement of the statute;
- d. FDA's criteria for GRAS classification are contrary to, less protective than, and do not reflect a permissible construction of the criteria in the FDCA;
- e. FDA did not and cannot explain how it can enforce the FDCA in light of the secret GRAS system and lack of recordkeeping requirements in the GRAS Rule; and
- f. FDA has failed to provide a "reasoned analysis" of why it interprets the "generally recognized as safe" exemption to allow for secret GRAS

determinations, and the use of chemical substances that are not “generally recognized” as “safe.”

VIII. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter an Order:

- (1) Declaring that the Defendants have violated the U.S. Constitution, the FDCA, and the APA by promulgating the GRAS Rule;
- (2) Declaring that the GRAS Rule is unlawful insofar as it does not require FDA to independently review GRAS determinations; does not require FDA to receive notice of GRAS determinations and their basis; does not require the public to receive notice of GRAS determinations and their basis; does not require manufacturers to maintain a record of GRAS determinations and their basis; and does not set forth criteria for GRAS status that are consistent with the FDCA.
- (3) Vacating the GRAS rule with directions to FDA to correct the legal deficiencies found by the court;
- (4) Retaining jurisdiction in this action to ensure compliance with its decree;
- (5) Awarding Plaintiffs attorney fees and all other reasonable expenses incurred in pursuit of this action; and
- (6) Granting other such injunctive and/or declaratory relief as the Court deems necessary, just and proper.

Respectfully submitted this 22nd day of May, 2017.

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