No. 20-70747

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

CENTER FOR FOOD SAFETY,

Petitioner,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al*.,

Respondents,

and

IMPOSSIBLE FOODS INC.,

Intervenor-Respondent.

ON PETITION FOR REVIEW FROM THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

PETITIONER'S COMBINED REPLY BRIEF

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INTRODUCTION

Color additives add no nutritional value to food; they are, just like they sound, only for appearance. For that reason, Congress intended they be subject to greater scrutiny by the U.S. Food and Drug Administration (FDA) than other food additives before they can be put in food. In furtherance of that congressional intent, FDA's color additive regulations require "convincing evidence" of safety, words that are notably absent from the agency's food additive regulations.

Despite the plain language distinction, it is not remotely clear what safety standard FDA applied in its review of soy leghemoglobin, Impossible Foods' novel color additive for which there is "no history or knowledge of human dietary exposure." 1-ER-081. For that reason alone, the Court should vacate FDA's decision. FDA's and Impossible Foods' attempts to conflate the two standards cannot escape the simple fact that one standard (color additive) requires "convincing evidence" while the other (food additive) does not.

FDA's decision also lacks substantial evidence in the record. The novelty of soy leghemoglobin and the large amount consumers are exposed to, place it in FDA's "highest probable risk to human health"

category, FER-004, which according to FDA's own authoritative guidelines should have triggered extensive toxicity testing, including subchronic, chronic, carcinogenicity, and reproductive testing. That did not occur. Instead, Impossible Foods submitted a study purporting to be a "subchronic toxicity" study, but which did not meet the minimum standards for such studies to warrant meaningful analysis. And even this deficient study produced suggestive evidence of health harms in test animals that also should have triggered additional, long-term testing, which again, did not happen.

For any or all of these reasons the Court should apply the default remedy and vacate FDA's unlawful color additive approval decision.

SUMMARY OF ARGUMENT

First and as an initial matter, Center for Food Safety (CFS) has standing, which Impossible Foods alone challenges. In its opening brief, CFS explained how FDA's approval of soy leghemoglobin as a color additive increases the risk of harm, thereby posing a credible food safety threat to CFS and its members. FDA increased that risk by using an improperly low legal threshold for its action, as well as relying on inadequate evidence. Op. Br. 32-56, ECF No. 19. Under the Ninth

Circuit's longstanding jurisprudence in probabilistic injury cases, such an increase in risk from the agency's unlawful approval action plainly satisfies the injury-in-fact requirement for Article III standing, which is the only prong that Impossible Foods challenges. This is also a procedural case, where FDA failed to properly respond to CFS's objections to the additive approval, a context where the standing showing is relaxed. Finally, CFS also has statutory standing, because its interests in food safety are far more than marginally related to and entirely consistent with the purposes of Section 721 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. § 379e, which is all that is required.

Second, FDA applied an incorrect, lower safety standard than required by its own color additive regulations when it approved soy leghemoglobin as a color additive. This violated the FFDCA. Under the FFDCA, FDA must presume that a color additive is *unsafe* unless the petitioner (here, Impossible Foods), supplies data establishing that its use will be safe. 21 U.S.C. § 379e(a), (b)(4). The burden of proof on petitioners seeking approval of new color additives is high: unlike its regulations for food additives, FDA's color additive regulations plainly

require "*convincing evidence* that establishes with reasonable certainty that no harm will result from the intended use of the color additive." 21 C.F.R. § 70.3(i) (emphasis added). FDA instead approved Impossible Foods' soy leghemoglobin under the lower standard for food additives. *See* 21 C.F.R. § 170.3(i).

FDA wrongly claims that any difference between the food additive and color additive regulations are "chiefly rhetorical." FDA Br. 21, ECF No. 30. Somewhat confusingly, Impossible Foods seems to agree with FDA that the standards of safety are similar, but at the same time admits that the standard of proof for color additives ("convincing evidence") is different. Int. Br. 29, 31, ECF No. 35. That not even FDA and Impossible Foods can agree on this vital point underscores CFS's argument that FDA's objection response was at best "vague, making it impossible . . . to determine" what standard of safety FDA actually used in reviewing Impossible Foods' petition. Op. Br. 41.

Regardless, neither FDA nor Impossible Foods can explain away the simple fact that in denying CFS's objections, FDA entirely omitted the "convincing evidence" test from the standard it applied, equating the safety standard of color additives with that of food additives and

GRAS substances. 1-ER-004. This was no "simple clerical error," Int. Br. 30, but rather indicative of FDA's systemic failure to apply the "convincing evidence" standard in its color additive regulations. 2-ER-152. By so doing, FDA based its approval of soy leghemoglobin on an incorrect, lower safety standard. And post hoc non-record rationale by either Respondent cannot explain that error away.

Third, FDA's approval of soy leghemoglobin lacks substantial evidence in the record, also violating the FFDCA. Under FDA's own authoritative guidelines, the high exposure level and extreme novelty of synthetic biology-created soy leghemoglobin mandate a *full battery* of toxicity tests, which it critically did not do. Estimated exposure to soy leghemoglobin *vastly exceeds* FDA's level that triggers the need for multiple long-term animal studies, including subchronic, chronic, carcinogenicity, and reproductive testing. FDA's guidelines also specifically states that novel color additives, like soy leghemoglobin, undergo a full battery of toxicity testing, regardless of exposure level. FDA's failure to mandate these studies for a novel color additive consumed in large quantities renders its decision without substantial evidence.

Fourth, lacking this full battery of toxicity testing, Respondents claim that the company's limited studies, including a 28-day rat-feeding study, were adequate.[1] FDA Br. 24; Int. Br. 33-42. But the 28-day rat-feeding study simply did not meet the minimum standards for either (1) study duration or (2) the number of test animals. And there is no evidence that Impossible Foods justified instead using a shorter timeframe or fewer animals.

Fifth, beyond its attempts to rehabilitate the improper toxicity study, Respondents seek to rely on the penumbra of the other information Impossible Foods submitted to FDA in order to meet its substantial evidence burden, such as the alleged safe history of both soy and soy leghemoglobin. FDA Br. 23; Int. Br. 42-43. Contrary to Impossible Foods' core claim, there is simply no "long history of safe consumption of . . . soy leghemoglobin protein." Int. Br. 1. And, as even FDA admits, as it must, the consumption history of *traditional* soy

[1] Impossible Foods submitted three studies to FDA. The first (Study 43167) was a 14-day study "to establish the dose range" for the second 28-day study (Study 43166). SER-32-33. The third study (Study 44856) was conducted to address "estrous cycle distributions observed in [the second study]," i.e., "disruptions in the reproductive cycle." SER-34, 1-ER-092. It is the second study (Study 43166) that FDA largely relied on and which is the subject of the briefing.

cannot be assumed to support the purported safety of the *novel color additive* soy leghemoglobin. 1-ER-081.

Sixth, Respondents now claim that a longer study with more animals compliant with FDA's own guidelines was unnecessary because soy leghemoglobin allegedly is "rapidly digested." Int. Br. 37; FDA Br. 25. But this was based on artificial tests involving highly acidic "simulated gastric fluid," which do not reflect the milder, less acidic conditions characterizing the stomachs of adults after meals, infants, the elderly, and those who take antacids. Translation: in real world conditions of many human stomachs, soy leghemoglobin will *not* be rapidly digested.

Seventh and finally, for these reasons, the Court should vacate the color additive approval, not simply remand it. In a case like this, where FDA applied the wrong legal standard, it is much more than a "technical" violation. Int. Br. 44. Rather, it goes to the agency's core legal duty to ensure that novel color additives are safe before they are sold. 21 U.S.C. § 379e. Leaving FDA's legally deficient decision in place risks more potential harm to public health than vacating it.

ARGUMENT

I. CFS HAS STANDING

As an initial matter, only Impossible Foods challenges standing; FDA does not. Moreover, even that dispute is narrow: Impossible Foods only challenges the injury-in-fact prong; it does not challenge causation or redressability grounds.

First, it is undisputed that the injury-in-fact prong is a low bar, for when agency procedural violations are at issue—such as an agency's failure to apply the correct legal standard in issuing a denial of CFS's color additive approval objections—for cognizable injury-in-fact, a petitioner only needs to show that (1) the agency violated certain procedural rules, (2) those rules protect petitioner's concrete interests, and (3) it is reasonably probable that the challenged action will threaten those concrete interests. *Citizens for Better Forestry v. U.S. Dep't of Agric.*, 341 F.3d 961, 969-70 (9th Cir. 2003); Int. Br. 23. Here, FDA violated its color additive procedures, which protect CFS's interests in health and food safety, and it is reasonably probable that FDA's improper decision will threaten those concrete interests.

Importantly, and contrary to Impossible Foods' framing, CFS need not assert that any specific injury will occur, but rather the injury is

that consumer safety consequences might be overlooked by the agency, as a result of the deficiencies in the government's analysis under food safety statutes. *Citizens for Better Forestry*, 341 F.3d at 971-72. The color additive provisions of the FFDCA and FDA's implementing regulations and processes are most certainly there to protect Petitioner's (and their members') interests in safe food. Yet, here for example because FDA did not apply the proper legal standard for color additive approvals, and instead improperly employed a lower one, it is reasonably probable that FDA may have overlooked health risks it otherwise would have flagged. Or, because FDA settled for a 28-day study instead of requiring a longer one pursuant to its own guidelines, it is reasonably probable that FDA may have overlooked health risks it otherwise would have found—and as discussed more below, it has. *See infra* 11-12, 37. Nothing more is required.

Further, once a petitioner seeking to enforce a procedural requirement establishes a concrete injury, "the causation and redressability requirements are relaxed." *WildEarth Guardians v. U.S. Dep't of Agric.*, 795 F.3d 1148, 1154 (9th Cir. 2015). "Plaintiffs alleging procedural injury must show only that they have a procedural right

that, if exercised, *could* protect their concrete interests." *Id.* (emphasis in original). Here, if FDA applied the proper legal standard to its review, it *might* reach a different result and deny the color additive approval.

Second and more generally, CFS has (1) suffered injury (2) fairly traceable to FDA's challenged conduct that is (3) redressable. *Friends of the Earth v. Laidlaw Envtl. Servs.*, 528 U.S. 167, 180-81 (2000). In a probabilistic injury case such as this, CFS does not need to show actual harm will occur but rather simply an "increased risk of harm" resulting from FDA's actions. *Ocean Advocs. v. U.S. Army Corps of Eng'rs*, 402 F.3d 846, 860 (9th Cir. 2005). The Ninth Circuit has "consistently held that an injury is 'actual or imminent' where there is a 'credible threat' that a probabilistic harm will materialize." *Nat. Res. Def. Council (NRDC) v. U.S. E.P.A.*, 735 F.3d 873, 878 (9th Cir. 2013).

Despite its shortcomings, a rat-feeding study commissioned by Impossible Foods nonetheless reveals such a credible threat to CFS's members (and through them, CFS organizationally), in numerous forms. These include a large number of statistically significant adverse effects, such as:

> (1) decreased reticulocyte (immature red blood cell) count, which can indicate anemia and/or bone marrow damage);
> (2) decreased blood clotting ability;
> (3) decreased blood levels of alkaline phosphate, which can indicate celiac disease and/or malnutrition;
> (4) increased blood albumin, which can indicate acute infections or tissue damage;
> (5) increased potassium levels, which can indicate kidney disease,
> (6) decreased blood glucose, which can indicate low blood sugar;
> (7) decreased chloride, which can indicate kidney problems;
> (8) and increased blood globulin values, which is common in inflammatory disease and cancer.

1-ER-091-92.[2] Despite the evident intent of Respondents to downplay these adverse effects as "incidental," both concede, for example, that "blood clotting ability," also referred to as "coagulation," was reduced in two treated groups of male rats, clearly a negative impact. FDA Br. 26;

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[2] *See also* Ctr. for Science in the Pub. Interest, *"Barebones" FDA Review of Impossible Burger's Soy Leghemoglobin Inadequate, Says CSPI* (Sept. 3, 2019) (explaining how the World Health Organization says there is "'strong evidence' that heme contributes to the carcinogenic mechanisms associated with red and processed meats" and that "both soy leghemoglobin and animal-based myoglobin release identical heme B molecules into the digestive system"), *available at* https://cspinet.org/news/barebones-fda-review-impossible-burger-soy-leghemoglobin-inadequate-20190903. The court may accept this for standing purposes. *See Nw. Envtl. Def. Ctr. v. Bonneville Power Admin.*, 117 F.3d 1520, 1528 (9th Cir. 1997) (court may consider extra-record evidence for purposes of standing).

2-ER-273, 2-ER-312.[3] In simple English, these health risks are shown in Respondent's own study about this novel color additive with no history of human consumption: risks of inflammatory disease, cancer, kidney disease, anemia, blood clotting, and celiac disease among them.

Further, CFS members are at an increased risk of harm from consuming soy leghemoglobin because Impossible Foods' "products are widely available in restaurants and supermarkets across the country." Int. Br. 44. Even if some of CFS's members are less likely to eat these products, some may choose to do so because they do not eat meat. And contrary to Impossible Foods' claim, Int. Br. 26-27, unilateral control over exposure to harm "does not necessarily render the harm nonspeculative." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 593 (1992).

Moreover, the number of Impossible Foods' products are *increasing*, Op. Br. 51-52, increasing the exposure risks, and many CFS members might not know that these products also contain soy leghemoglobin unless they read the ingredient list on the product label.

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[3] Molecular geneticist Michael Antoniou, PhD, confirms that the statistically significant difference conceded by Impossible Foods and FDA was in fact a *decrease* in blood clotting ability in treated rats. 1-ER-092.

As stated above, all of CFS's declarants that have previously eaten Impossible Foods' meatless burger said they did so *without knowing* that it contained soy leghemoglobin. *See* Kaluza Decl. ¶ 6; Kelley Decl. ¶¶ 7-8; Maker Decl. ¶ 5; Thomas Decl. ¶ 10. It stands to reason that many other CFS members have done the same and will continue, especially with an expanding product line.

That expanding product line will also require these and other CFS members to take proactive steps to research product labels in stores or online to make sure they are not purchasing products that have undergone limited safety testing that could increase risks of kidney disease, inflammatory disease, and cancer. 1-ER-092. This also is a cognizable injury-in-fact. *See Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 153-56 (2010) (standing found where members took "certain measures to minimize the likelihood" of potential harm).

Third, Impossible Foods also gets the legal standard for injury-in-fact wrong, citing this Court's decision in *In re Zappos.com, Inc.*, 888 F.3d 1020 (9th Cir. 2018) and the D.C. Circuit's decision in *Food & Water Watch v. Vilsack*, 808 F.3d 905 (D.C. Cir. 2015). *See* Int. Br. 26. Both of these cases relied on the Supreme Court's decision in *Clapper v.*

Amnesty Int'l USA, 568 U.S. 398 (2013). As this Court has explained, the standing showing in *Clapper* was "especially rigorous" because it arose in a sensitive national security context. *In re Zappos.com*, 888 F.3d at 1026. This Court has subsequently used the "credible threat" standard in other contexts not involving national security, including cases like this involving public health. *See, e.g.*, *NRDC*, 735 F.3d at 878.

Moreover, the extra-circuit *Food & Water Watch* is inapposite to this Court's "credible threat" standard, *see NRDC*, 735 F.3d at 878, a standard instead consistent with the approaches of other circuits in similar cases. In *Baur v. Veneman*, for example, the Second Circuit explained that "[l]ike threatened environmental harm, the potential harm from exposure to dangerous food products or drugs 'is by nature probabilistic,' yet an unreasonable exposure to risk may itself cause cognizable injury." 352 F.3d 625, 634 (2d Cir. 2003). Indeed, the "very purpose of the . . . FFDCA . . . is to ensure the safety of the nation's food supply and to minimize the risk to public health from potentially dangerous food and drug products." *Id.*

Finally, contrary to Impossible Foods' claim, Int. Br. 28-29, CFS also has statutory standing. Statutory standing turns on simply

whether CFS's interests "are arguably protected by" Section 721 of the FFDCA. *See Nw. Requirements Utils. v. FERC*, 798 F.3d 796, 807-08 (9th Cir. 2015). As long as CFS's interests are not "so marginally related to or inconsistent with the purposes implicit in the statute," CFS has statutory standing. *Id.* at 808.

Under Section 721, Congress declared that color additives are unsafe unless FDA issues a regulation prescribing the conditions under which the additive may be safely used. 21 U.S.C. § 379e(a). CFS's organizational interests in food safety, the consumer's right to know what's in the food they eat, and the public health are easily more than marginally related to and consistent with the safe regulation of color additives. *See* Hanson Decl. ¶¶ 3-20. Therefore, in addition to having Article III standing, CFS also has statutory standing.

II. FDA FAILED TO APPLY THE CONVINCING EVIDENCE STANDARD TO IMPOSSIBLE FOODS' COLOR ADDITIVE PETITION.

As CFS explained in its opening brief, Congress intended FDA to subject color additives to *greater* scrutiny than food additives. Op. Br. 16-19, 32-43. This is evident from the fact that Congress did not include a GRAS exemption like it did for food additives. *Id.* at 17-18. It is also

evident from the plain language of FDA's regulations implementing the Color Additives Amendment, in which the agency required "*convincing evidence* that establishes with reasonable certainty that no harm will result from the intended use of the color additive." 21 C.F.R. § 70.3(i) (emphasis added). FDA failed to apply the convincing evidence standard in its review and approval of Impossible Foods' petition.

The plain text of the regulations, the statutory scheme and legislative history, multiple canons of construction, all support CFS's interpretation: that the color additive standard is different, and higher, than the food additive standard. Op. Br. 32-39. Yet FDA claims that the differences in wording between the two standards are "chiefly rhetorical." FDA Br. 21. Impossible Foods seemingly agrees, but elsewhere acknowledges that the "burden of proof" is different for color additives. Int. Br. 5. But this is a distinction without a difference: the burden of proof required is part and parcel of what the legal standard is. These semantics cannot obfuscate the fact that, by their plain language, the standards of safety *are* different, with color additives requiring more to establish safety ("convincing evidence") than food additives. *See* Op. Br. 19, 34-39; 21 C.F.R. §§ 70.3(i), 170.3(i). More

fundamentally, Respondents' inconsistency on this key point supports CFS's argument that FDA's objection response was at best "vague, making it impossible . . . to determine" what standard of safety FDA used in its review of Impossible Foods' petition. Op. Br. 41 (quoting *Nw. Coal. for Alts. to Pesticides (NCAP) v. U.S. E.P.A.*, 544 F.3d 1043, 1051 (9th Cir. 2008) (EPA failed to explain its departure from established safety factor)).

Contrary to Impossible Foods' claim, FDA's failure to apply the convincing evidence standard was no "simple clerical error." Int. Br. 30. Rather, it is a systemic problem at FDA in which the agency blurs the lines for these distinct regulatory programs. *See* 1-ER-004 (FDA explaining that it considers the standards of safety for color additives, food additives, and GRAS substances to be "the same"); 2-ER-152 (guidance document omitting "convincing evidence" from standard of safety for color additives). In FDA's review of Impossible Foods' first GRAS notice, the agency stated that the notification "should adequately address" the safety of soy leghemoglobin. 1-ER-081. "Should adequately address" is not "the same" as "convincing evidence that establishes with reasonable certainty that no harm will result from the intended use of

the color additive." 21 C.F.R. § 70.3(i). But according to FDA, the standards of safety for color additives, food additives, and GRAS substances are indistinguishable. 1-ER-004. This is contrary to the plain language of 21 C.F.R. § 70.3(i) and renders its decision "vague, making it impossible . . . to determine" what standard of safety FDA used. *See NCAP*, 544 F.3d at 1051.

As CFS explained, Congress intended that color additives be subjected to greater scrutiny than food additives. Op. Br. 32-34. Unlike for food additives, there is no GRAS exemption for color additives. *Id.* 32-33. This reflected the intent that FDA be "particularly careful" with color additives because they add "no value at all" to food beyond "eye appeal." *Id.* 17, 33. The plain language of FDA's regulations reflect this institutional caution, requiring "convincing evidence" to establish safety, words that are noticeably absent from the food additive safety standard. *Id.* 34-35. And multiple canons of construction make clear that the distinct terms used in the two standards be given different meaning. *Id.* 35-39.

FDA also relies on two out-of-circuit cases claiming that CFS "does not deny the enormous amount of data submitted under testing already

done fails to show *any* evidence that these color additives are not safe." FDA Br. 21-22 (emphasis in original) (citation omitted). This is inaccurate. CFS cited numerous "statistically significant differences" in observed health effects in Impossible Foods' 28-day feeding study. Op. Br. 53-54 (including differences that could indicate anemia and/or damage to bone marrow, tissue damage, kidney disease, and cancer); 1-ER-005, 1-ER-092. "[T]he fact that there were so many statistically significant changes in multiple organs and systems suggests that closer scrutiny of the safety of [soy leghemoglobin] is urgently required." 1-ER-093.

Moreover, the out-of-circuit cases that FDA cites do not support its position. The "enormous amount of data" discussed in *McIlwain v. Hayes*, 690 F.2d 1041, 1048 (D.C. Cir. 1982), concerned FDA's review of twenty-three color additives that were already "commercially established" when Congress passed the Color Additive Amendments in 1960. *Id.* at 1043. The Color Additive Amendments created a transitional process in which these commercially established color additives could remain in food while the industry completed newly required safety testing. After repeated extensions of the transitional

period in 1971, 1977, and 1981, consumer groups sued FDA for failing to issue final rules for these twenty-three color additives. *Id.* at 1044-45.

The court stated, however, that FDA's extensions were reasonable in this case because testing methodologies kept advancing so rapidly that by the time FDA would review industry safety data for these color additives, "ever-improving scientific techniques for testing" required additional safety studies. *Id.* at 1044. Thus, by the time the D.C. Circuit decided this case in 1982, FDA had an "enormous amount of data" from decades of scientific testing for these twenty-three color additives. *Id.* at 1044-45, 1048.

Here, we are most definitively not dealing with twenty-three "commercially established" color additives for which there is an "enormous amount of data" based upon decades of testing: quite the opposite. Rather, soy leghemoglobin is a very novel and new color additive for which there is *no* previous history of safe use. 1-ER-081. And FDA failed to require long-term studies recommended by its own guidelines, and the 28-day rat-feeding study did not adhere to those guidelines either. *Infra* 23-33. When considered in context, CFS's claims

can hardly be characterized as "little more than nitpicking." FDA Br. 23 (citation omitted).

FDA also cites *Public Citizen v. Young*, 831 F.2d 1108 (D.C. Cir. 1987), claiming that this Court need not even consider the differences between the safety standards for color additives and food additives. FDA Br. 22. That is not what the court in *Public Citizen* held. Rather, the court discussed the differences between the Delaney Clauses of the Food Additive Amendments and Color Additive Amendments. *Public Citizen*, 831 F.2d at 1118-1122. Notably, the court stated that although the clauses have similar wording, "the context is clearly different" for each. *Id.* at 1120. Like the Delaney Clauses at issue *Public Citizen*, the context for the standards of safety for color additives and food additives "is clearly different." *Id.*; *see* Op. Br. 11-19, 32-43.

First, Congress did not include a GRAS exemption for color additives as it did for food additives. *Compare* 21 U.S.C. § 321(s) (food additives), *with* § 321(t) (color additives); *see also* Op. Br. 18. This reflects the fact that, unlike food additives, color additives provide "no value at all" to food, "except so-called eye appeal." *Color Additives Amendment of 1960: Hearings on H.R. 7624 and S. 2197 Before the H.*

Comm. on Interstate and Foreign Commerce, 86th Cong., 2d Sess. 108 (1960) (statement of Rep. James Delaney of New York); *see also* Op. Br. 17-18.

Second, FDA itself understood that the context between these safety standards "is clearly different" when it promulgated the color additive regulations. FDA decided that the requisite standard of safety for color additives is "convincing evidence," words that are notably absent from the standard of safety for food additives. *Compare* 21 C.F.R. § 70.3(i) *with* 21 C.F.R. § 170.3(i). The Court should reject FDA's and Impossible Foods' attempts to rewrite the color additive safety standard.

III. FDA FAILED TO SUPPORT ITS DECISION WITH SUBSTANTIAL EVIDENCE.

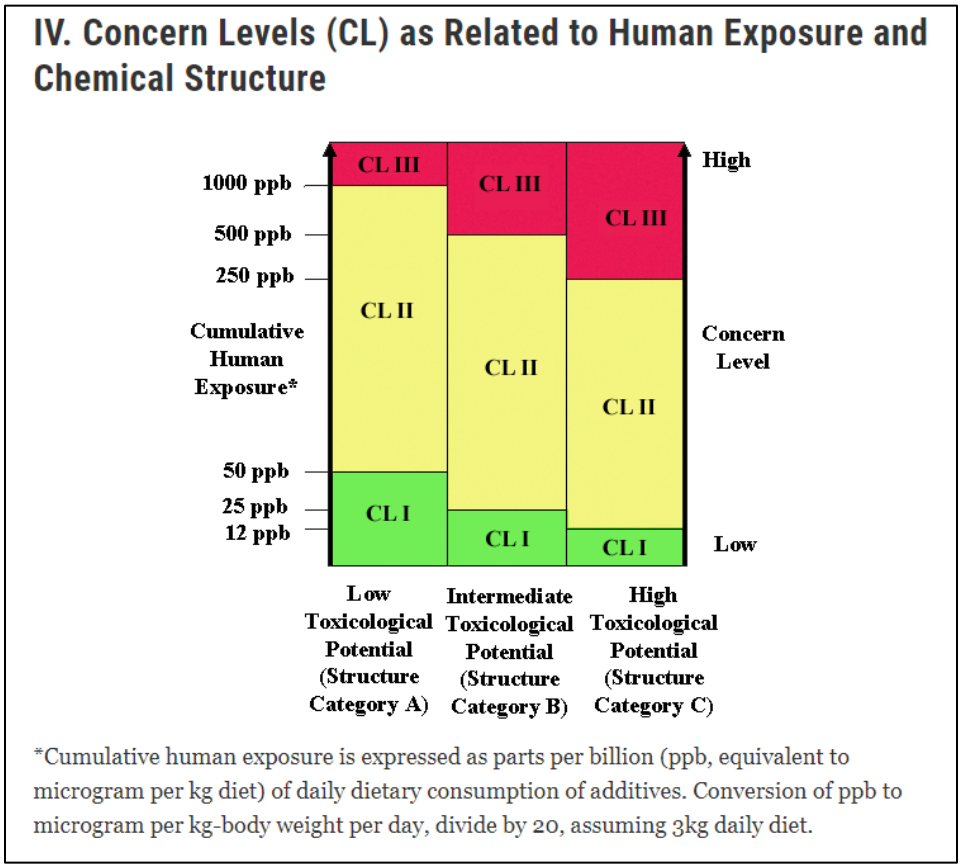
FDA and Impossible Foods claim that the agency supported its decision with substantial evidence. Both largely rely on Impossible Foods' submission of a rat-feeding study that did not comply with the minimum standards called for in FDA guidance regarding the length of time and number of animals for such studies. *See* FDA Br. 22-27; Int. Br. 33-42. FDA and Impossible Foods further claim that even without this inadequate rat-feeding study, FDA supported its decision with

substantial evidence. *See* FDA Br. 23; Int. Br. 42-43. Contrary to these claims, FDA's decision was not supported by substantial evidence.

A. The estimated exposure and novelty of soy leghemoglobin should have prompted rigorous testing.

Importantly, Respondents do not dispute the fact that, according to the Redbook, soy leghemoglobin falls into Concern Level III (CL-III) by virtue of its extremely high level of estimated consumption. *See* Op. Br. 50-51, n.23. Concern levels are "relative measures of the degree to which the use of an additive may present a hazard to human health," with CL-III representing "the *highest probable risk to human health*." FER-004 (emphasis added). FDA determines Concern Levels based on human exposure to and chemical structure of the additive:

Figure 1: Concern Levels (CL) as Related to Human Exposure and Chemical Structure.[4]



[4] FDA, *Guidance for Industry: Summary Table of Recommended Toxicological Testing for Additives Used in Food*, *available at* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-summary-table-recommended-toxicological-testing-additives-used-food. FDA explains that the determined Concern Level "translates to the *minimum* set of recommended toxicity tested needed to evaluate the toxicological safety of the new or expanded use of the additive." *Id.* (emphasis added).

Once a concern level is determined, this "translates to the *minimum* set of recommended toxicity tests needed to evaluate the toxicological safety of the new or expanded use of the additive."[5]

Even if an additive has low toxicological potential (Structure Category A), FDA nevertheless considers the additive to trigger CL-III if the human exposure to it exceeds 1,000 parts per billion (ppb) in food, equivalent to 50 micrograms per kg-body weight per day (µg/kg bw/d), assuming a 3kg daily diet. *See* Figure 1; Op. Br. 51, n.23. As CFS previously explained, assuming that soy leghemoglobin falls into the lowest (safest) of three toxicological potential categories (Structure Category A), the mean estimated intake of soy leghemoglobin still exceeds the trigger for CL-III testing by a factor of nearly 100, and by over 200 for consumers in the 90th percentile of exposure. *See* Op. Br. 51, n.23, 2-ER-296 (Table 4); Figure 1.

Nor does FDA or Impossible Foods deny that "the minimum set of recommended toxicity tests needed to evaluate the toxicological safety" of a CL-III substance such as soy leghemoglobin includes not only subchronic but also chronic, carcinogenicity, and reproductive toxicity

[5] *Id.*; *see also* Figures 1 and 2.

studies, among others. Op. Br. 50-51; Figure 2. Thus, not only should Impossible Foods have conducted a subchronic toxicity study for at least 90 days to 12 months, it also should have conducted a full battery of toxicity testing as shown in Figure 2 below:

Figure 2: Recommended Toxicological Testing Summary Table for Additives Used in Food.[6]

III. Recommended Toxicological Testing Summary Table for Additives Used in Food

Toxicity Tests[3]	Concern Level Low (I)	Level Intermediate (II)	Concern Level High (III)
Genetic Toxicity Tests	X	X	X
Short-term toxicity tests with rodents	X[c]	X[a,c]	X[a,c]
Subchronic toxicity studies with rodents		X[c]	X[a,c]
Subchronic toxicity studies with non-rodents		X[c]	X[a,c]
One-year toxicity studies with non-rodents			X[c]
Chronic toxicity or Combined chronic toxicity/carcinogenicity studies with rodents			X[c]
Carcinogenicity studies with rodents			X
Reproduction studies		X[c]	X[c]
Developmental toxicity studies		X[b,c]	X[b,c]
Metabolism and Pharmacokinetic studies (available in PDF (90 KB)from 1993 Draft Redbook II)		X[b]	X[b]
Human studies (available in PDF (86 KB)from 1993 Draft Redbook II)			X[b]

a If needed as preliminary to further study.
[b]If indicated by available data or information
[c]Including screens for neurotoxicity and immunotoxicity (available in PDF (156 KB) from 1993 Draft Redbook II).

The need for a full battery of testing is further supported by the fact that soy leghemoglobin is a novel protein. Int. Br. 12; 1-ER-091,

[6] FDA, *Guidance for Industry: Summary Table of Recommended Toxicological Testing for Additives Used in Food*, *available at* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-summary-table-recommended-toxicological-testing-additives-used-food.

SER-41. According to FDA, The "[m]inimum toxicological testing recommended to support the safety of a novel additive might include studies generally recommended for a Concern Level III additive, *irrespective of its chemical structure and exposure*."[7] In other words, even if an additive has the lowest possible Concern Level, if it is a novel additive, FDA says it should be considered CL-III in terms of toxicity testing. Of course, here we not only have a novel additive that, in and of itself, should have triggered CL-III testing, but a novel additive for which the estimated daily intake vastly exceeds the trigger for CL-III testing even assuming it has the lowest toxicological potential (Structure Category A).

B. Impossible Foods' 28-day rat-feeding study with only ten animals per sex per dosage group did not meet FDA's *minimum* requirements for subchronic toxicity studies.

Both FDA and Impossible Foods' claim that the company's 28-day rat-feeding study with only 10 rats per sex per group was sufficient for

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[7] FDA, *Guidance for Industry: Summary Table of Recommended Toxicological Testing for Additives Used in Food* (emphasis added), *available at* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-summary-table-recommended-toxicological-testing-additives-used-food.

demonstrating the safety of a substance that "has not been used in food before." FDA Br. 24-25; Int. Br. 39-42; 1-ER-073. Both point to FDA's testing guidelines in the Redbook as not being binding to support the notion that a genetically engineered substance never before consumed by humans did not warrant longer-term studies with more test subjects to demonstrate safety. FDA Br. 22-27; Int. Br. 35-39. Regardless of whether the Redbook is technically binding, the FDA guidance nevertheless lays out detailed minimum standards for food safety testing that warrant respect from the Court. *See Pollinator Stewardship Council v. EPA*, 806 F.3d 520, 531-32 (9th Cir. 2015) (EPA cannot ignore standards it set itself); *NRDC*, 735 F.3d at 883-84 (same).

As FDA explains, one of its core responsibilities "is to ensure the safety of food ingredients added to the food supply in the United States." 2-ER-152. In developing the Redbook to help ensure food safety, FDA solicited input from "the regulated and scientific communities" and "considered publications and information regarding recent advances and increased knowledge in toxicology, science and the food industry, and other authoritative guidance for toxicity testing." 2-ER-152. The study protocols in the Redbook thus represent FDA's considered

judgment "to assist petitioners and notifiers" in, *inter alia*, "designing, conducting, and reporting the results of toxicity studies." 2-ER-151. As such, the Redbook's study protocols warrant this Court's respect.[8] *Pollinator Stewardship*, 806 F.3d at 531-32; *NRDC*, 735 F.3d at 883-84.

One of those study protocols, found in Chapter IV.C.4.a., sets out the parameters for conducting subchronic toxicity studies in rodents. 2-ER-267-77. According to this protocol, "[s]ubchronic toxicity studies with rodents are generally conducted for 90 days (3 months), but they may be conducted for up to 12 months." 2-ER-267; *see also* FDA Br. 25 (acknowledging "90-day" baseline for "subchronic studies"). "Any other regime [for testing duration] must be justified." 2-ER-270.

In addition to testing duration, Chapter IV.C.4.a. sets out specific parameters for the number and sex of rodents used for subchronic toxicity studies. For such studies, "experimental and control groups should have at least 20 rodents per sex per group." 2-ER-268. FDA says that "ten rodents/sex/group may be acceptable for subchronic rodent

[8] And while Impossible Foods now insists that the Redbook guidelines "are not *requirements*," Int. Br. 41, it previously identified these guidelines as a "data requirement." SER-72.

studies" but only "when the study is considered to be range-finding in nature or when longer term studies are anticipated." 2-ER-268.

Here, Impossible Foods submitted a study that it claims was designed and conducted in conformance with the "data requirements" contained in Redbook section IV.C.4.a. for subchronic toxicity studies with rodents. SER-32, SER-72, SER-94, SER-103, SER-118, 2-ER-267. That means the study should have been conducted for *at least* 90 days *unless* Impossible Foods "justified" using a shorter timeframe. 2-ER-267, 2-ER-270. The study also should have included "*at least* 20 rodents per sex per group" unless the study was considered to be "range-finding in nature"[9] or if the company planned to conduct "longer term studies." 2-ER-268 (emphasis added).

But Impossible Foods' rat-feeding study did not satisfy these parameters. Far from it, the study was conducted for just 28 days, not

[9] A "range-finding" study is a "preliminary exploratory stud[y]" to gather information such as dose range to facilitate proper design of a subsequent laboratory study. FDA, *Good Laboratory Practice Regulations Management Briefings, Post Conference Report*, Subpart A – General Provisions, #23 (Aug. 1979), *available at* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/good-laboratory-practice-regulations-management-briefings-post-conference-report-aug-1979.

even one-third of the 90-day minimum duration that Section IV.C.4.a. of the Redbook calls for. SER-32, 2-ER-267, 2-ER-270. At no point in the record prior to FDA's decision did Impossible Foods explain why this much shorter duration was "justified." 2-ER-270.

Second, the study included just 10 rats per sex per group, just half of the minimum number that Section IV.C.4.a. calls for. SER-33, 2-ER-268. This number of animals may have been acceptable if this had been a "range-finding" study. But it was not. Nor were there any longer term studies conducted or in the record. In other words, not only did Impossible Foods fail to "justify" cutting the duration of its study from the 90-day minimum to just 28 days, it also failed to provide any justification in the record prior to FDA's decision for reducing the minimum number of rats by half.

Recognizing these failures, FDA belatedly claims that Impossible Foods mistakenly "labeled" its rat-feeding study as a 90-day subchronic study. FDA Br. 25. This is the first time that FDA has relied on this rationale and it should be rejected by the court as post-hoc rationalization. *See Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 212 (1988) (responsibility for elaborating on agency orders lies with

administration officials, not appellate counsel); *Altamirano v. Gonzales*, 427 F.3d 586, 595 (9th Cir. 2005). And even assuming the study was mistakenly labeled as a "subchronic" study, FDA fails to identify what kind of study it was.

Regardless, the argument is unpersuasive as Impossible Foods not only labeled the study as meeting the data requirements of Section IV.C.4.a. multiple times, SER-72, SER-94, SER-103, SER-118, but also explained within the study itself that it "*was designed to meet the guidelines* in the US FDA Toxicological Principles for the Safety Assessment of Food Ingredients, Redbook 2000, IV.C.4.a. *Subchronic* Toxicity Studies with Rodents (2007)." SER-32 (emphasis added). And Impossible Foods still maintains that position. Int. Br. 41. That Respondents cannot even agree on whether or not this study was a "subchronic" toxicity study indicates how fatally flawed FDA's whole review process was. FDA Br. 25; Int. Br. 41.

Without a compliant subchronic toxicity study, FDA failed to support its decision with any of the recommended studies for novel CL-III color additives. *Supra* 27 (Figure 2).

C. History of consumption of soy and soy leghemoglobin does not constitute substantial evidence.

FDA and Impossible Foods claim that, regardless of whether the rat-feeding study constitutes substantial evidence, other information that Impossible Foods submitted still constitutes substantial evidence to support FDA's decision. FDA Br. 23; Int. Br. 42-43. Both point, for example, to the history of consumption of soy leghemoglobin and substances similar to soy leghemoglobin. Neither is persuasive.

First, Impossible Foods claims that "the long history of safe consumption of soy, soy leghemoglobin protein, and *P. pastoris*" constitutes substantial evidence for FDA's decision. Int. Br. 42; *accord* FDA Br. 23. First, there is no "long history of safe consumption of . . . soy leghemoglobin protein" extracted from the roots of soy plants. Int. Br. 1. Indeed, soy leghemoglobin "has not been used in food before" and "there is no history or knowledge of human dietary exposure to soy leghemoglobin from roots" at all, a fact that Impossible Foods later admits in its brief. 1-ER-073, 1-ER-081; Int. Br. 8 ("there is no specific history of humans consuming soy root nodules"). Impossible Foods cannot have its cake and eat it too.

Second, FDA and Impossible Foods cannot consider the history of consumption of *soy* to support the purported safety of *soy leghemoglobin*. As FDA has explained, "[a]lthough proteins are a part of the human food supply, not all proteins are safe" and "[i]nformation addressing the safe use of modified soy protein does not adequately address safe use of soybean leghemoglobin from the roots of the soybean plant in food." 1-ER-081. And contrary to FDA's litigation position parroting Impossible Foods' claim that the safety of soy leghemoglobin is partially demonstrated by the safety of proteins that are structurally or functionally similar, FDA Br. 16, the agency's scientific reviewers previously rejected this very argument. 1-ER-045 ("conformational similarity or functional similarity among proteins is not an indication of the safety of proteins for consumption").

D. FDA and Impossible Foods present no substantial evidence for claim that soy leghemoglobin is "rapidly digested" in the stomach.

FDA's and Impossible Foods' "rapid digestion" pretext for not requiring subchronic and longer toxicity studies is contradicted by experts that FDA itself relied on in its review of Impossible Foods' petition. FDA Br. 25; Int. Br. 37. However, the so-called "rapid

digestion" of soy leghemoglobin proteins is based not on actual digestion in the stomach but rather on an artificial (*in vitro*) test using simulated gastric fluid (SGF), an acidic solution containing the digestive enzyme pepsin. 2-ER-328. The results of these SGF tests say nothing about whether and how quickly soy leghemoglobin would be digested in most human stomachs. In fact, the reference material relied upon by FDA makes clear that this *in vitro* pepsin test "was not designed to mimic human digestion and, therefore, cannot predict the half-life of a protein *in vivo* [in stomachs]." FER-042.[10]

Moreover, many proteins that digest in highly acidic SGF tests are quite stable under the far milder, less acidic conditions characterizing the stomachs of adults after meals, infants, the elderly, and those who take antacids. FER-18, FER-33.[11] In other words, the experts that FDA

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[10] The source of this quote is the Bannon 2004 study listed in the references for FDA's toxicology review of Impossible Foods' color additive petition. *See* 2-ER-320-35. This study should be considered part of the record as FDA relied on it in its review of Impossible Foods' petition. Even if not considered part of the record, it nevertheless is "necessary to explain technical terms or complex subject matter" and should be admitted. *See San Luis & Delta-Mendota Water Auth. v. Jewell*, 747 F.3d 581, 656 (9th Cir. 2014).

[11] The sources of this statement are the Untersmayr and Jensen-Jarolim 2008 and Pekar et al. 2018 studies consulted by FDA for its

cited make clear that proteins, like soy leghemoglobin, may well survive digestion in millions of people whose stomachs do not reflect the highly acidic conditions in the SGF test that Impossible Foods used, thus undermining the argument that there was no "added utility" for a longer study. FDA Br. 25; Int. Br. 37.

FDA does admit that Impossible Foods "located irregularities in female rats' estrous cycles (involving their reproductive systems)" and observed "[d]ecreases in uterine weight" in its 28-day study. FDA Br. 24; 2-ER-324. As a result, Impossible Foods "conducted a second 28-day study" that did not replicate these irregularities and, according to FDA, this "confirmed" that there were no "adverse effects." FDA Br. 24; *see also* 2-ER-324-326, 1-ER-092. However, that the second test did not replicate the same irregularities is not a confirmation of anything, particularly given its similar short duration and the paucity of animals tested. 1-ER-091. If anything, all that having two similarly deficient

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toxicology review of Impossible Foods' color additive petition. *See* 2-ER-320-35. These studies should be considered part of the record as FDA relied on them in its review of Impossible Foods' petition. Even if not considered part of the record, the studies nevertheless are "necessary to explain technical terms or complex subject matter" and should be admitted. *See San Luis & Delta-Mendota Water Auth.*, 747 F.3d at 656.

studies with different outcomes show is that FDA still lacked substantial evidence to support its conclusion. Rather, these limited studies only highlight the urgent need for a full battery of CL-III toxicity testing (1-ER-093; Figure 2), including a reproductive study that would more definitively assess soy leghemoglobin's effects on a full range of female and male reproductive parameters over several generations of rodents. FER-003-014.

For these reasons, FDA's decision is not supported by substantial evidence.

IV. THE COURT SHOULD VACATE FDA'S DECISION.

As Petitioners explained in their opening brief, in these administrative law circumstances vacatur is the default, presumptive remedy if the Court grants the petition for review and holds FDA violated the law. *See* Op. Br. 56-58 (and citations therein). Remand without vacatur is only appropriate in "limited circumstances," *Pollinator Stewardship*, 806 F.3d at 532, or "rare circumstances," *Humane Soc'y of U.S. v. Locke*, 626 F.3d 1040, 1053 n.7 (9th Cir. 2010). As such, importantly, Respondent FDA has the burden, *not* Petitioners, to show why equity demands the remedy be anything *other* than

vacatur. *All. for the Wild Rockies v. U.S. Forest Serv.*, 907 F.3d 1105, 1121-22 (9th Cir. 2018) ("presumption of vacatur," unless defendants meet their burden to show otherwise); *Idaho Farm Bureau Fed'n v. Babbitt*, 58 F.3d 1392, 1405 (9th Cir. 1995) (vacatur applies unless "equity demands" otherwise).

The Ninth Circuit analyzes whether this is one of those "rare" cases of remand without vacatur by "weighing the seriousness of the agency's errors against the disruptive consequences" of the decision. *Nat'l Family Farm Coal. v. EPA*, 960 F.3d 1120, 1144 (9th Cir. 2020) (quoting *Pollinator Stewardship*, 806 F.3d at 532). In this case Respondents have not met their heavy burden to show this is one of those rare cases—that the agency's error of law is not serious enough, or the disruptive consequences are so great—that the Court should not simply vacate the unlawful approval and remand.

First, FDA does not address the proper core vacatur/remand without vacatur stated above and in Petitioner's opening brief. Instead it begins by misapplying *Pollinator Stewardship*, speculating what might happen on remand, namely that FDA might again approve this color additive. FDA Br. 28; *see also* Int. Br. 44 (same argument). But

Pollinator Stewardship rejected that same remand without vacatur argument and instead *vacated* when EPA—analogous to FDA here—failed to comply with its own regulations and undertake a study. 806 F.3d at 532.

Contrary to FDA's mis-framing, the only on remand issue relevant to the "seriousness of the error" inquiry is whether the "*same rule* would be adopted on remand," meaning the *exact same action*. *Id.* (emphasis added). If "a different result *may* be reached," after remand, nothing more is required to vacate. *Id.* Here, on remand FDA will have to apply the proper legal standard of convincing evidence. It will have to look at further evidence of the color additive's safety. Whatever future decision it might make, it will not be the exact "same" decision.

More generally, the issue is the seriousness of the agency's error. Applying the wrong legal standard and evidentiary threshold—substituting the lower food additive one for the higher color additive convincing evidence standard—goes to the core of FDA's FFDCA duties in this area. This is not just a mere "technical" violation, as Impossible claims. Int. Br. 44. Rather one would be hard pressed to think of a more serious and fundamental violation.

FDA then argues that vacatur is not warranted because Petitioner had the burden to present FDA with further independent studies showing harm. FDA Br. 28. This is irrelevant and incorrect two ways. First, as explained above, it is not Petitioner's burden in the vacatur context, it is *Respondents*, to produce evidence showing why anything other than vacating the unlawful approval is warranted. *See supra* 39. Second, even as to the agency's statutory burden, it is not Petitioner's burden to produce the evidence needed to demonstrate that soy leghemoglobin is safe. That burden is on the color additive petitioner, here Impossible Foods. 21 U.S.C. § 379e; 21 C.F.R. § 71.1.[12]

Respondent FDA also mentions the "disruptive consequences" of vacatur being Impossible Foods having to cease marketing foods until and unless FDA issues a lawful color additive approval. FDA Br. 29; *see also* Impossible Br. 44. Impossible Foods claims, without any showing

[12] In any event, the procedure that FDA references for requesting scientific studies is unavailing. That procedure ostensibly allows "any interested person" to request FDA "to conduct scientific studies to support a petition for a regulation for a color additive." 21 C.F.R. § 70.55. However, by its terms, this section refers to studies "to *support*" a color additive petition. *Id.* (emphasis added). As such, the regulation appears intended for those entities in the food industry that may support a color additive petition.

in support, that vacatur would be "highly disruptive." Such conclusory speculation cannot meet their high burden.

More fundamentally, this is a case about health and safety, and a substance with no history of human consumption. And when fashioning equitable relief, courts must look to the purpose of the statute in question, *Amoco Prod. Co. v. Village of Gambell*, 480 U.S. 531, 543-43 (1987), and here the purpose of the statute is protecting the public health, 21 U.S.C. § 379e, not economic considerations. The health consequences are consequences that are the touchstone of the inquiry and allegations of economic disruption alone are insufficient in this context, if not coupled with evidence showing that remand without vacatur is better for the public health. Rather vacatur is warranted because from a public health perspective, leaving FDA's decision in place "risks more potential [health] harm than vacating it." *Pollinator Stewardship*, 806 F.3d at 532; *accord All. for Wild Rockies*, 907 F.3d at 1122. In *National Family Farm Coalition v. EPA*, the pesticide companies alleged billions of dollars in economic harm, and the Court said it was "aware of the adverse impact" to thousands of farmers who had already bought the pesticide, but nonetheless vacated it, because

that was the environmentally protective remedy. 960 F.3d 1123, 1144-45 (9th Cir. 2020). Respondents have not shown that leaving the color additive on the market despite an unlawful approval is more protective of the public health, nor could they here. Consequently vacatur is appropriate.

Finally Impossible Foods apes FDA in arguing that Petitioner had the extraordinarily burden to show a "customer experiencing an adverse health effect" has already occurred in order for the Court to simply vacate. Int. Br. 44. Again, that attempts to completely reverse the basic standard. This is not an injunction. This is simply vacating an unlawful agency action and resetting the *status quo ante*, the presumptive remedy when an agency approval is held to violate the law. In these exact circumstances—where there is unknown risk because of the failure of an agency to analyze properly—this Court vacates. *Pollinator Stewardship*, 806 F.3d at 532 (because agency failed to undertake proper study, it had "no real idea" whether pesticide would cause harm to bees and vacated); *All. for Wild Rockies*, 907 F.3d at 1121-22 (vacating because defendants left some environmental risks "not addressed" and "unexplained").

Respondents have the burden to produce evidence to show why this is the rare circumstance where that is not the appropriate remedy and have not come close to meeting that burden.

For these reasons the Court should vacate the approval.

CONCLUSION

For the reasons stated above, Petitioner requests the Court vacates FDA's decision, and remands for further proceedings consistent with this Court's decision.

Respectfully submitted this 28th day of January, 2021.

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