CENTER FOR FOOD SAFETY

September 3, 2019

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Objections and Request for Hearing Regarding FDA's Listing of Color Additives Exempt From Certification—Soy Leghemoglobin; Docket No. FDA-2018-C-4464 , 21 C.F.R. Part 73

Dear Commissioner:

Center for Food Safety (CFS), on behalf of its 950,000 members and supporters, submits this objection and request for hearing in response to the Food and Drug Administration's (FDA) final rule: "Listing of Color Additives Exempt From Certification; Soy Leghemoglobin." See 84 Fed. Reg. 37573 (Aug. 1, 2019). FDA proposes to approve this new color additive that is derived from the genes of soy leghemogloblin inserted into *Pichia pastoris,* a yeast that lives on methanol. The resulting genetically engineered product contains both the DNA of the soy "heme" and the DNA of the *P. pastoris* and other chemicals used to stabilize the preparation.

CFS's mission is to empower people, support farmers, and protect the environment from harmful industrial agriculture, while supporting sustainable ecological and organic farming. CFS takes a multi-faceted approach in pursuing its mission, utilizing legal, political, and grassroots strategies, including public and policymaker education, outreach, and campaigning. CFS disseminates a wide array of informational materials to government agencies, lawmakers, nonprofits, and the general public regarding the adverse effects of industrial food production on public health, the environment, farmers, and on transparency in the food system. These educational and informational materials include, but are not limited to, news articles, videos and other multimedia, policy reports, white papers, legal briefs, press releases, newsletters, product guides, action alerts, and fact sheets.

OBJECTIONS AND REQUEST FOR A HEARING

In accordance with 21 C.F.R. § 12.22, CFS respectfully files the following objections and requests a hearing on each:

Objection 1: FDA should not have approved this product to be used in ground beef analogues that are not plant-based without additional safety testing and public comment.

Objection 2: FDA should require labeling of this color additive as "soy leghemoglobin/*P. pastoris* yeast protein."

Objection 3: FDA should have required additional testing of the raw product.

WASHINGTON D.C. OFFICE
660 Pennsylvania Avenue, SE Suite 402
Washington, D.C. 20003
T: 202-547-9359 F: 202-547-9429

CALIFORNIA OFFICE
303 Sacramento Street, 2nd Floor
San Francisco, CA 94111
T: 415-826-2770 F: 415-826-0507

PACIFIC NORTHWEST OFFICE
2009 NE Alberta Street, Suite 207
Portland, OR 97211
T: 971-271-7372

office@centerforfoodsafety.org centerforfoodsafety.org

Objection 4: FDA improperly relied on Impossible Foods' GRAS Notice 737 instead of independently verifying the safety of SLH for use as a color additive.

Objection 5: FDA should have required separate testing of *Pichia pastoris* as it is genetically engineered

Objection 6: FDA violated NEPA by failing to prepare an environmental assessment or environmental impact statement.

LEGAL BACKGROUND

Under the Federal Food, Drug, and Cosmetic Act (FFDCA), "[a] color additive shall . . . be deemed unsafe . . . unless . . . there is in effect, and such additive and such use are in conformity with, a regulation issued under [21 U.S.C. § 379e(b)] listing such additive for use[.]" 21 U.S.C. § 379e(a). A "color additive" is:

> any material, not exempted under section 201(t) of the [FFDCA], that is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source and that, when added or applied to a food . . . is capable (alone or through reaction with another substance) of imparting a color thereto.

21 C.F.R. § 70.3(f); *see* 21 U.S.C. § 321(t)(1). Any such additive must either be from a batch certified for such use or, with respect to such use, be exempted from the certification requirement. 21 U.S.C. § 379e(a).

FDA cannot list a color additive for a proposed use "unless the data . . . establish that such use, under the conditions of use specified in the regulations, will be safe[.]" 21 U.S.C. § 379e(b)(4). In determining whether a proposed use of a color additive is safe, FDA must consider:

i. The probable consumption of, or other relevant exposure from, the additive and of any substance formed in or on food . . . because of the use of the additive;
ii. The cumulative effect of such additive in the diet of man or animals, taking into account the same or any chemically or pharmacologically related substance or substances in such diet;
iii. Safety factors that are generally recognized by qualified experts as appropriate for the use of animal experimentation data; and
iv. The availability of any needed practicable methods of analysis for determining the identity and quantity of (1) the pure dye and all intermediates and other impurities contained in such color additive, (2) such additive in or on any article of food, and (3) any substance formed in or on such article because of the use of such additive.

21 U.S.C. § 379e(b)(5)(A). Regulations implementing 21 U.S.C. § 379e(b)(5)(A)(iii) further provide that "in determining whether the proposed use of a color additive will be safe . . . a safety factor of 100 to 1 will be used in applying animal experimentation data to man[.]" 21 C.F.R. § 70.40. In other words, "a color additive for use by man will not be granted a tolerance

that will exceed 1/100th of the maximum no-effect level for the most susceptible experimental animals tested." *Id*. In addition, FDA must "require the presentation of all needed scientific data in support of a proposed listing to assure that each listed color additive will be safe for its intended use or uses in or on food[.]" 21 C.F.R. § 70.42(a).

REGULATORY AND PROCEDURAL HISTORY

In September 2014, Impossible Foods submitted a GRAS notice to FDA asserting that soy leghemoglobin (SLH) is GRAS for its intended use. *See* Impossible Foods GRAS Notice (Sept. 4, 2014). In October 2014, FDA acknowledged receipt of Impossible Foods' GRAS notice and assigned it as GRAS Notice No. 000540. *See* FDA Receipt Letter (Oct. 2, 2014).

On April 8, 2015, FDA identified a series of questions and comments regarding GRN 540. *See* Impossible Burger FOIA Documents, pp. 62-63 (Ex. 1), *retrieved from* https://1bps6437gg8c169i0y1drtgz-wpengine.netdna-ssl.com/wp-content/uploads/2017/08/072717_Impossible_Burger_FOIA_documents.pdf. For example, FDA stated that:

> Although proteins are a part of the human food supply, not all proteins are safe. Information [provided in GRN 540] addressing the safe use of modified soy protein does not adequately address safe use of soybean leghemoglobin protection from the **roots** of the soybean in food.
>
> [. . .]
>
> The dietary exposure discussion in GRN 540 includes history of safe use of soy proteins from the soybean plant in general and does not discuss soy leghemoglobin from the roots of the soybean plant, which is the ingredient described in the GRAS notice. The discussion is not relevant in the context of the GRAS notice because soybean root is not a commonly consumed human food. Please provide relevant information, as there is no history or knowledge of human dietary exposure to soy leghemoglobin from roots.

Id. at 62 (emphasis in original).

In May 2015, Impossible Foods responded to FDA's concerns, stating that although "the [SLH] protein is isolated from the root nodule, it is substantially similar to proteins consumed daily by the global population, in the form of meat and other vegetables" and "there is no evidence to suggest that [SLH] in food will behave any differently from the myriad other functionally equivalent and widely consumed globin proteins in the human diet." *Id*. at 2, 4. Impossible Foods also enlisted Richard E. Goodman at the University of Nebraska's Food Allergy Resource and Research Program (FARRP) "to assess the potential allergenicity of [SLH] as well as other hemoglobin proteins derived from a variety of plants and bacterial sources[.]" *Id*. at 7.

On August 3, 2015, FDA had a phone conversation with Impossible Foods' employees regarding GRN 540. Minutes from the call reveal that "FDA believe[d] that the arguments presented [by Impossible Foods], individually and collectively, do not establish the safety of

SLH for consumption, nor do they point to a general recognition of safety[.]" *Id*. at 26. In particular, FDA stated that:

- Conformational similarity or functional similarity among proteins is not an indication of the safety of proteins for consumption.
- Just belonging to the globin family does not guarantee that the protein will be safe to consume.
- Binding oxygen and other similar molecules (CO, NO) is the function of all respiratory proteins. Such function has nothing to do with the safety of the proteins for consumption.
- Analyses using other software, such as SVM module-based software, indicate that SLH could be an allergen.
- [T]he list of proteins (~20-25% of the final product) co-purified with the SLH raises further question on how the safety argument could be made based solely on SLH."

Id. Two weeks later, Steve Taylor, a consultant hired by Impossible Foods who had also served on a previous GRAS panel for GRN 117 (ice-structuring protein), submitted comments on the potential allergenicity of SLH. *Id*. at 35-36. According to Mr. Taylor, labeling would reduce the risk to existing soy-allergic people and there was "appropriate documentation of a low risk for increased allergenenicity" in GRN 540. *Id*. at 36.

However, on November 10, 2015, Impossible Foods sent a letter to FDA requesting the agency withdraw GRN 540 and that the company will submit a subsequent "application for review in the future, with additional supportive information." *Id*. at 28.

In January 2016, Impossible Foods requested a meeting with FDA to discuss filing another GRAS notice for SLH protein derived from *Pichia pastoris*. *Id*. at 29-34. Impossible Foods asked FDA whether the agency would agree to a 90-day oral feeding study in rats to assess the systemic toxicology of SLH at doses of 125, 250, and 500 mg/kg/day in a sample of 10 animals/sex. *Id*. at 30. Impossible Foods also reiterated the opinions of Richard Goodman and Steve Taylor regarding the potential allergenicity of SLH and asked for FDA's concurrence with those opinions to "support the safety of leghemoglobin." *Id*. at 31-32.

In February 2016, FDA met with Impossible Foods employees to discuss the "company's potential approach to address FDA suggestions after withdrawal of GRN 000540." *Id*. at 53. During the meeting:

> FDA staff asked for clarification on whether the substance currently being discussed differs from the substance previously reviewed under GRN 0540. Impossible Foods staff stated that the current composition of the substance slightly differs from the product detailed in GRN 0540. They stated that their production methods have been evolving during the scaling up process, resulting in changes to the composition of the final soy leghemoglobin product.
>
> FDA then provided feedback on the toxicology aspects of a safety study used to support a conclusion of GRAS status. FDA emphasized that in general, GRAS status requires demonstration of both safety as well as general recognition of that safety. FDA noted that the product being discussed in [sic] an ingredient that **has not been used in food before**.

Id. at 54 (emphasis added). In a slide presentation dated the same day as this meeting, Impossible Foods discussed the issue of allergenicity of SLH. *Id*. at 51. However, FDA redacted information "concerning an assessment of leghemoglobin reactivity with soy-allergic individuals," claiming it is protected as a trade secret and commercial or financial information obtained from Impossible Foods that is privileged or confidential. *Id*.

In August 2016, Impossible Foods sent a letter to FDA regarding safety testing of SLH. *Id*. at 55. The letter references the earlier February 2016 meeting between FDA and Impossible Foods and the plans to "complete a 90-day feeding study in rodents, to support the safety of [SLH]." *Id*. However, Impossible Foods stated that "[a]fter consideration of the Agency's feedback during the meeting, Impossible Foods has decided to conduct a 28-day study" instead with "doses of 250, 500, and 750 mg/kg bw/day." *Id*. Impossible Foods sought confirmation from FDA "that this dose schedule is acceptable." *Id*.

In September 2016, FDA responded as follows:

> It is necessary to emphasize that we cannot provide confirmation that a study – which has not yet been conducted – will support the safety of a product in a GRAS conclusion. We cannot offer such assurances in advance of the conduct of the study. As you are aware, the safety assessment supporting a GRAS conclusion involves multiple types of information, not just a feeding study . . . The support of one dosing study cannot be assessed independently of the other types of information . . . In regards to the time frame of the study, we do not provide specific suggestions such as this to a notifier for a GRAS notice.

Id. at 56.

In October 2017, with a new administration in office, Impossible Foods submitted a second GRAS notice for SLH, which FDA designated as GRN 000737. *See* FDA No Questions Letter (July 23, 2018). In July 2018, FDA said it had "no questions" regarding Impossible Foods' conclusion that SLH is GRAS for its intended use. *Id*. However, FDA also noted that the use of SLH preparation in food products sold for retail may constitute a color additive and that its "no questions" letter "is not an approval for use [of heme] as a color additive nor is it a finding of the Secretary . . . within the meaning of [21 U.S.C. § 379e(b)(4)]." *Id*.

On October 16, 2018, Impossible Foods submitted a petition proposing that the color additive regulations be amended to provide for the safe use of SLH as a color additive in plant-based, non-animal derived ground beef analogue products. *See* Dep't of Health & Human Servs., *Memorandum – CAP 9C0314; Petition for the use of soy leghemoglobin from Pichia pastoris as a color additive in ground beef analogue products* (June 20, 2019) ("June 2019 FDA Memo"). FDA published a notice of Impossible Foods' filing in December 2018. *See Impossible Foods, Inc.; Filing of Color Additive Petition*, 83 Fed. Reg. 64045 (Dec. 13, 2018). On August 1, 2019, FDA published a final rule amending the color additive regulations to provide for the purportedly safe use of heme as a color additive in ground beef analogue products. *See* 84 Fed. Reg. 37573 (Aug. 1, 2019).

Objection 1: FDA should not have approved this product to be used in ground beef analogues that are not plant-based without additional safety testing and public comment.

When FDA published notice of Impossible Foods' petition, the agency stated that the petition proposes to amend the color additive regulations to provide for the use of SLH as a color additive in "plant-based, non-animal derived ground beef analogue products." 83 Fed. Reg. 64045, 64046 (Dec. 13, 2018). At the request of Impossible Foods, however, FDA changed the final rule (21 C.F.R. § 73.520(c)) to allow the use of SLH in *all* ground beef analogue products, not just in plant-based ground beef analogue products. *See* 84 Fed. Reg. 37573, 37576 (Aug. 1, 2019) (SLH may be used "in ground beef analogue products such that the amount of [SLH] does not exceed 0.8 percent by weight of uncooked ground beef analogue product.").

This change would allow SLH to be used in new cell-based products without additional testing for allergenicity in such new forms of "meats." Impossible Foods' safety testing of its genetically engineered heme, however, was based on its use with the company's *soy*-based ground beef analogue and that is the extent to which FDA's review and approval should go. FDA's approval to expand the use of SLH in all ground beef analogue products requires additional testing for allergenicity. Therefore, CFS objects and requests a hearing on FDA's change in the final rule at 21 C.F.R. § 73.520(c) that allows the use of SLH in all ground beef analogue products, not just plant-based ground beef analogue products.

Objection 2: FDA should require labeling of this color additive as "soy leghemoglobin/*P. pastoris* yeast protein."

Color additives "shall be labeled with sufficient information to assure their safe use and to allow a determination of compliance with any limitations imposed by [21 C.F.R. Parts 70, 71, 73, 74, 80, and 81]." 21 C.F.R. § 70.25(a). Color additive labels shall state: (1) the name of the straight color or the name of each ingredient comprising the color additive, if it is a mixture; (2) a statement indicating general limitations for the use of the color additive, such as "for food use only"; (3) where regulations impose quantitative limitations for a general or specific use of a straight color, the amount of each such straight color in terms of weight per unit/volume or percent by weight; and (4) an expiration date if stability data require it. *Id*. The labeling approved by FDA does not provide "sufficient information" about Impossible Foods' product.

FDA originally proposed labeling Impossible Foods' product as containing "soy leghemoglobin preparation." *See* FDA, Memorandum of Telephone Conversation, at 1 (Apr. 12, 2019). In the final rule, however, FDA approved Impossible Foods' request to use only "soy leghemoglobin" on the label. FDA says this is because, "[a]ccording to the petitioner, 'soy leghemoglobin' is consistent with the way they are currently marketing the substance, and it is the name with which consumers are familiar." FDA, Srinivasan Memorandum, at 10 (June 20, 2019) (hereafter, "Srinivasan Memo").

Labeling decisions for color additives must be based on providing "sufficient information to assure their safe use." 21 C.F.R. § 70.25(a). This requires FDA to defer on the side of accuracy and transparency, not a company's marketing plan. The fact that "consumers are familiar" with how Impossible Foods "is currently marketing the substance" does not mean that those consumers have "sufficient information" about the substance to assure it is safely used.

Both the FDA and Impossible Foods assert that the final product contains DNA derived proteins of both soy leghemoglobin and *P. pastoris.* In fact, FDA says that the safety evaluation conducted by Impossible Foods (rather than the agency) referred to "the consumption of soy leghemoglobin protein and *P. pastoris* proteins in the LegH Prep[.]" FDA, Supratim Choudhuri Memorandum, at 2 (June 21, 2019) (hereafter, "Choudhuri Memo"). Consumers should know that both are present in case they believe that they have allergies to either soy products or yeast products. Therefore, CFS objects and requests a hearing on the labeling of this color additive. CFS proposes calling this color additive "soy leghemoglobin/*P. pastoris* yeast protein."

Objection 3: FDA should have required additional testing of the raw product.

Impossible Foods' GRAS conclusion in GRN 737 was for the use of soy leghemoglobin preparation to optimize flavor in ground beef analogue products "intended to be cooked." *See* FDA No Questions Letter (July 23, 2018); 84 Fed. Reg. at 37574. FDA assumes that the product will be fully cooked before eating, thereby reducing the risk of allergic reactions. However, many people will likely eat their "burgers" rare and, with this heme, making them "bleed." Since it is reasonably foreseeable that many consumers will not fully cook this analogue product, FDA should have required additional allergenicity testing of preparation as present in the rare or raw product. Therefore, CFS objects and requests a hearing on FDA's failure to require additional testing of the raw product as part of its safety evaluation.

Objection 4: FDA's reliance on Impossible Foods' GRAS Notice 737 violates the definition of "safe" in 21 C.F.R. § 70.3(i).

The FFDCA establishes a pre-market safety review process in which the burden is on the manufacturer to prove that a color additive is safe before it can be added to food and sold to consumers in retail stores. *See* 21 U.S.C. § 379e(a). There is no GRAS exception to the color additive petition process. *Compare* 21 U.S.C. § 321(s) *with* 21 U.S.C. § 321(t). Thus, in order to market products containing color additives, manufacturers must seek and receive FDA's approval, which must be based on the statutory factors in 21 U.S.C. § 379e. Further, FDA defines "safe" in the context of color additives to mean that "there is convincing evidence that establishes with reasonably certainty that no harm will result from the intended use of the color additive." 21 C.F.R. § 70.3(i).

The record demonstrates that FDA relied heavily on Impossible Foods' GRAS Notice filed in a separate proceeding (and under a separate statutory provision) instead of independently verifying the safety of SLH for use as a color additive. In doing so, FDA substituted Impossible Foods' self-interested analysis for the government's public interest safety review, inserting a de facto GRAS exception into the color additive petition process where none exists.

FDA cites just two references (the Srinivasan and Choudhuri memos) that it relied on for its approval of Impossible Foods' petition. *See* 84 Fed. Reg. at 37576. The Srinivasan memo notes that "[t]he subjects of GRN 737 and CAP 9C0314 are the same" and that the Srinivasan memo "refer[s] to information available in GRN as applicable in [FDA's] review of CAP 9C0314." Srinivasan Memo at 1. The Choudhuri memo summarizes various rat studies that were conducted in support of GRN 737. *See* Choudhuri Memo at 4-7. Of the 20 references cited in the

Choudhuri memo in support of CAP 9C0314, 13 of those references were from Impossible Foods' GRN 737.

It is well-established that the GRAS process is plagued with problems of transparency and conflict-of-interest. The Government Accountability Office (GAO) has stated that "FDA's oversight process does not help ensure the safety of all new GRAS determinations" and "FDA is not systematically ensuring the continued safety of current GRAS substances." GAO, *Food Safety: FDA Should Strengthen Its Oversight of Food Ingredients Determined to Be Generally Recognized as Safe (GRAS)*, at 8, 20 (Feb. 2010), https://www.gao.gov/new.items/d10246.pdf. GAO also expressed concern about FDA's failure to develop guidance to help manufacturers avoid conflicts of interest. *Id*. at 14-15. As a result, "FDA does not know whether the [GRAS] determinations of companies' expert panels are arrived at independently." *Id*. at 15. A 2011 study focusing on conflicts of interest in GRAS decisions found that, among 451 GRAS notices voluntarily submitted to FDA, all the GRAS determinations were made by either an employee of an additive manufacturer, an employee of a consulting firm selected by a manufacturer, or by an expert panel selected by the manufacturer or a firm that was a consultant to the manufacturer. *See* Thomas G. Neltner, et al., *Conflicts of Interest in Approvals of Additives to Food Determined to Be Generally Recognized as Safe*, JAMA Intern. Med., at 3 (Aug. 7, 2013) (Ex. 2).[1]

These conflicts pervaded GRN 737 and have bled over into CAP 9C0314. For example, two of the references FDA relied on in the Choudhuri memo that were not included in GRN 737, are more recent studies (2018) that were co-authored by Impossible Foods employees or consultants. *See* Choudhuri Memo at 15. The first study (Safety Evaluation of Soy Leghemoglobin Protein Preparation Derived From *Pichia pastoris*, Intended for Use as a Flavor Catalyst in Plant-Based Meat) was co-authored by three Impossible Foods' employees. The second study (Evaluating Potential Risks of Food Allergy and Toxicity of Soy Leghemoglobin Expressed in *Pichia pastoris*) was co-authored by one Impossible Foods' employee and one of the company's consultants.[2] FDA's substantial reliance on Impossible Foods' filings in GRN 737 and more recent studies conducted by Impossible Foods' employees and consultants, rather than conducting its own safety analyses, undermines the integrity of the color additive petition process.

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[1] *See also* Ctr. for Food Safety, et al. v. Azar, No. 17-cv-3833 (filed May 22, 2017) (challenging FDA's final rule "Substances Generally Recognized as Safe," 81 Fed. Reg. 54960 (Aug. 17, 2016)).

[2] The consultant, Richard E. Goodman, works at the University of Nebraska's Food Allergy Research and Resource Program (FARRP), https://farrp.unl.edu/dr-richard-e-goodman-research-professor, and previously worked for Monsanto, the company behind the development of GMO soy beans that Impossible Foods' recently announced it was switching to as it scales up production. *See* Louisa Burwood-Taylor, *Impossible Foods In Full Scale-Up Mode With Burger Manufacturing Deal and FDA Approval*, Forbes (July 31, 2019), https://www.forbes.com/sites/louisaburwoodtaylor/2019/07/31/impossible-in-full-scale-up-mode-with-new-burger-manufacturing-deal--fda-approval/#78d6035671a1.

For example, Impossible Foods originally planned to conduct a 90-day feeding study in rats but reduced this to just 28 days after receiving "feedback" from FDA. *See* Ex. 1 at 55. This raises concern because "the shorter the duration of a study, the less likely it is to find health effects such as organ damage, which take time to show up." Claire Robinson and Michael Antoniou, *Rat Feeding Study Suggests the Impossible Burger May Not Be Safe to Eat*, GMO Science (June 25, 2019), https://www.gmoscience.org/rat-feeding-studies-suggest-the-impossible-burger-may-not-be-safe-to-eat/ (Ex. 3). Robinson and Antoniou (2019) also noted that "[t]here were too few animals in each test group (10 per sex per group)" in the 28-day study and, coupled with that short duration, failed "to clarify any health concerns from long-term consumption of this product." *Id*.

Even so, Robinson and Antoniou (2019) found it "remarkable that the SLH-fed rates did show a large number of statistically significant potentially adverse effects, compared with the control group[.]" Id. This included changes in blood chemistry, decreased blood clotting ability, and increased blood globulin values. *Id*. "The fact that these changes were seen in spite of the statistical weaknesses of the study gives particular reason for concern" and "suggests that closer scrutiny of the safety of SLH is urgently required." *Id*.

Therefore, CFS objects to and requests a hearing on FDA's failure to provide convincing evidence that provides reasonable certainty (and is free from conflicts of interest) that **no harm** will result from the use of SLH. 21 C.F.R. § 70.3(i).

Objection 5: FDA should have required separate testing of *Pichia pastoris* as it is genetically engineered

While *P. pastoris* was reviewed in GRN 000204, that GRAS determination suffers from the same kinds of conflict and transparency issues that were discussed above.[3] Moreover, GRN 000204 involved varieties of the yeast that do not use the kind of genetic engineering that the Impossible Foods' preparation contains. Only one other yeast product—§73.355 *Phaffia* yeast—is approved as a food colorant. The *Phaffia* approval required extensive testing of the kind of yeast used as the colorant. The Impossible Foods' genetically engineered *P. pastoris*, as expressed in this form of the yeast, should also require separate testing for allergenicity as the genetically-engineered yeast proteins are present in the final "soy leghemoglobin/*P. pastoris* preparation." Therefore, CFS objects and requests a hearing on FDA's failure to require separate testing of the genetically engineered *P. pastoris* yeast.

Objection 6: FDA violated NEPA by failing to prepare an environmental assessment or environmental impact statement.

The National Environmental Policy Act (NEPA) is our "national charter for protection of the environment." 40 C.F. R. § 1500.1(a). Its purpose is to "promote efforts which will prevent or eliminate damage to the environment." 42 U.S.C. § 4321. Regulations promulgated by the Council on Environmental Quality (CEQ) implement NEPA and govern FDA's decision-making. *See* 40 C.F.R. §§ 1500-1508; 21 C.F.R., Part 25.

[3] FDA also approved dried *P. pastoris* as a food additive in 1993 but only in animal feed, not for human consumption. *See* 21 C.F.R. § 573.750.

When enacting NEPA, Congress expressed great concern for the "profound impact of man's activity on the interrelations of all components of the natural environment, particularly the profound influences of . . . new and expanding technological advances . . ." 42 U.S.C. § 4331(a). Congress was specifically wary of "[a] growing technological power which is far outstripping man's capacity to understand and control its impact on the environment." S. Rep. No. 91-296, 91st Cong., 1st Sess., at 6, 1969 U.S. Code Con. & Admin. News 1969.

The twin pillars of NEPA are the requirements that agencies (1) carefully evaluate the environmental impacts of proposed actions before undertaking the action, and (2) fully advise the public of the potential impacts of those actions, and of alternatives. NEPA requires federal agencies to fully consider and disclose the environmental consequences of an agency action before proceeding with that action – to take a "hard look." 42 U.S.C. § 4332(2)(C); 40 C.F.R. §§ 1501.2, 1501.4, 1502.5. An agency's evaluation of environmental consequences must be based on "accurate scientific" information and "high quality." 40 C.F.R. § 1500.1(b). If there are not sufficient data available, the agency must follow the requisite procedure for addressing or evaluating the impacts in view of incomplete or unavailable information. *Id*. § 1502.22.

Impossible Foods claims that its petition is categorically excluded from the requirement for an EA or an EIS because "soy leghemoglobin would be added directly to food and is intended to remain in food through ingestion by consumers and is not intended to replace macronutrients in food." *See* 83 Fed. Reg. at 64046. Impossible Foods further alleges that, "to their knowledge, no extraordinary circumstances exist." *Id*. FDA accepted Impossible Foods' rationale and "determined that this action is categorically excluded" and, as a result, "neither an environmental assessment nor an environmental impact statement is required." 84 Fed. Reg. at 37575.

Under FDA's regulations, "[a]pproval of a . . . color additive petition . . . for substances added directly to food that are intended to remain in food through ingestion by consumers and that are not intended to replace macronutrients in food" may be categorically excluded from documentation in an EA or EIS. 21 C.F.R. § 25.32(k). However, "FDA will require at least an EA for any specific action that ordinarily would be excluded if extraordinary circumstances indicate that the specific proposed action may significantly affect the quality of the human environment[.]" 21 C.F.R. § 25.21. Examples of extraordinary circumstances include but are not limited to:

- Actions for which available data establish that, at the expected level of exposure, there is the potential for serious harm to the environment; and
- Actions that adversely affect a species or the critical habitat of a species determined under the Endangered Species Act or the Convention on International Trade in Endangered Species of Wild Flora and Fauna to be endangered or threatened or wild flora and fauna that are entitled to special protection under some other Federal law.

Id. Here, FDA failed to consider whether there may be indirect and cumulative adverse effects to threatened and endangered species or their critical habitat as a result of its approval of Impossible Foods' petition.

Indirect effects are "caused by the action and are later in time or farther removed in distance, but are still reasonably foreseeable." 40 C.F.R. § 1508.8(b). "Indirect effects may include growth inducing effects and other effects related to induced changes in the pattern of land use, population density or growth rate, and related effects on air and water and other natural systems, including ecosystems." *Id*. Cumulative effects are the effects that result from "the incremental impact of the action when added to other past, present, and reasonably foreseeable future actions regardless of what agency (Federal or non-Federal) or person undertakes such other actions." 40 C.F.R. § 1508.7. "Cumulative impacts can result from individually minor but collectively significant actions taking place over a period of time." *Id*.

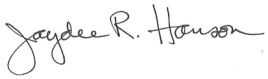
Earlier this year, Impossible Foods "famously switch[ed] from wheat to GM soy . . . for the Impossible Burger 2.0." *See* Louisa Burwood-Taylor, *Impossible Foods In Full Scale-Up Mode With Burger Manufacturing Deal and FDA Approval*, Forbes (July 31, 2019), https://www.forbes.com/sites/louisaburwoodtaylor/2019/07/31/impossible-in-full-scale-up-mode-with-new-burger-manufacturing-deal--fda-approval/#78d6035671a1. In so doing, Impossible Foods "will ironically increasingly compete with the livestock sector for feedstock." *Id*. "[T]he U.S. grocery store launch [in September 2019] is likely [Impossible Foods'] biggest priority" because "[n]ow [that] Impossible Foods has received FDA approval of heme [as a color additive], it can sell directly to consumers." Jessi Devenyns, Impossible Burgers are coming to grocery shelves in September," Food Dive (Aug. 1, 2019), https://www.fooddive.com/news/impossible-burgers-are-coming-to-grocery-shelves-in-september/559952/. Thus, FDA's approval of Impossible Foods' petition was an integral component of the company's plans to increase production, which will increase the use of GMO soy and actually compete with the livestock industry for feedstock. If there is no appreciable reduction in beef consumption with the Impossible Burger on the market (in restaurants and stores), then it is possible that it will not reduce environmental impacts but add to them.

For example, according to Claire Robinson and Dr. Michael Antoniou, a closer look at the ingredients of the Impossible Burger (including SLH) reveals that nearly all of them are highly processed. Claire Robinson and Dr. Michael Antoniou, *The Impossible Burger: Boon or Risk to Health and Environment?*, GMO Science (May 16, 2018), https://www.gmoscience.org/impossible-burger-boon-risk-health-environment/ (Ex. 4). These industrial processes are "energy-hungry and materials-hungry" and "that's without considering the environmental footprint of the pesticides and fertilizer applied to the non-organic crops that go into making the Impossible Burger." *Id*. It is important to note that this article was published *before* Impossible Foods' announced that it was replacing the textured wheat protein in the original Impossible Burger with soy protein concentrate from GMO soybeans.

The spraying of pesticides like Monsanto's dicamba on GMO crops, including soy, has resulted in myriad environmental effects. *See e.g.*, Ctr. for Food Safety, Monsanto Seeks to Expand Use of Devastating Herbicide to GMO Corn (Mar. 19, 2019), https://www.centerforfoodsafety.org/press-releases/5540/monsanto-seeks-to-expand-use-of-devastating-herbicide-to-gmo-corn. For example, EPA has admitted that spraying dicamba may harm protected plant and animal species. *See* EPA, *Ecological Risk Assessment for Dicamba and its Degradate, 3,6-dichlorosalicylic acid (DCSA), for the Proposed New Use on Dicamba-Tolerant Soybean (MON 87708)* (Mar. 8, 2011) (Ex. 5). FDA should have considered these

potential indirect and cumulative effects on these species from increased pesticide application on GMO soy. Thus, CFS objects and requests a hearing on FDA's decision to categorically exclude Impossible Foods' petition from review in an EA or EIS.

Respectfully submitted,



Jaydee Hanson
Policy Director
Center for Food Safety
660 Pennsylvania Ave., SE, #402
Washington, DC 20003
(202) 547-9359
jhanson@centerforfoodsafety.org

Ryan Talbott
Staff Attorney
Center for Food Safety
2009 NE Alberta St., Suite 207
Portland, OR 97211
(971) 271-7372
rtalbott@centerforfoodsafety.org