The Rule

This amendment to Title 14 Code of Federal Regulations (14 CFR) part 71:

Removes the Class E airspace designated as an extension to a Class C surface area at Lafayette Regional Airport/Paul Fournet Field, Lafayette, LA, as it is no longer required;

Amends the Class E airspace designated as a surface area at Lafayette Regional Airport/Paul Fournet Field by amending the header of the airspace legal description from ''Lafayette Regional Airport, LA'' to ''Lafayette, LA'' to comply with FAA Order 7400.2M, Procedures for Handling Airspace Matters; updating the name and geographic coordinates of Lafayette Regional Airport/Paul Fournet Field (previously Lafayette Regional Airport) to coincide with the FAA's aeronautical database; and updating the outdated term ''Airport/Facility Directory'' with ''Chart Supplement'';

And amends the Class E airspace extending upward from 700 feet above the surface to within a 7.5-mile radius (decreased from a 7.7-mile radius) of the Lafayette Regional Airport/Paul Fournet Field; within a 6.7-mile radius (decreased from a 6.9-mile radius) of Acadiana Regional Airport, New Iberia, LA; updates the names of Lafayette Regional Airport/Paul Fournet Field (previously Lafayette Regional Airport), Abbeville Chris Crusta Memorial Airport (previously Abbeville Municipal Airport), and Acadiana Regional Airport (previously Acadiana Regional) to coincide with the FAA's aeronautical database; and updates the geographic coordinates of Lafayette Regional Airport/Paul Fournet Field to coincide with the FAA's aeronautical database; and removes the city associated with the Acadiana Regional Airport from the airspace legal description to comply with a change to FAA Order 7400.2M, Procedures for Handling Airspace Matters.

This action is the result of an airspace review caused by the decommissioning of the Acadi NDB, which provided navigation information for the instrument procedures at Acadiana Regional Airport and the development of new instrument procedures at Lafayette Regional Airport/Paul Fournet Field.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures,'' paragraph 5–6.5.a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11D, Airspace Designations and Reporting Points, dated August 8, 2019, and effective September 15, 2019, is amended as follows:

Paragraph 6002 Class E Airspace Areas Designated as Surface Areas.

* * * * *

ASW LA E2 Lafayette, LA [Amended]

Lafayette Regional Airport/Paul Fournet Field, LA
(Lat. 30°12′18″ N, long. 91°59′16″ W)

Within a 5-mile radius of the Lafayette Regional Airport/Paul Fournet Field. This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Chart Supplement.

Paragraph 6003 Class E Airspace Areas Designated as an Extension to a Class C Surface Area.

* * * * *

ASW LA E3 Lafayette, LA [Removed]

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ASW LA E5 Lafayette, LA [Amended]

Lafayette Regional Airport/Paul Fournet Field, LA
(Lat. 30°12′18″ N, long. 91°59′16″ W)
Abbeville Chris Crusta Memorial Airport, LA
(Lat. 29°58′33″ N, long. 92°05′03″ W)
Acadiana Regional Airport, LA
(Lat. 30°02′16″ N, long. 91°53′02″ W)

That airspace extending upward from 700 feet above the surface within a 7.5-mile radius of Lafayette Regional Airport/Paul Fournet Field, and within a 6.4-mile radius of Abbeville Chris Crusta Memorial Airport, and within a 6.7-mile radius of Acadiana Regional Airport.

Issued in Fort Worth, Texas, on December 11, 2019.

Steve Szukala,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2019–27276 Filed 12–18–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. FDA–2018–C–4464]

Listing of Color Additives Exempt From Certification; Soy Leghemoglobin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; response to objections and denial of public hearing requests; removal of administrative stay.

SUMMARY: The Food and Drug Administration (FDA or we) is responding to objections that it received from the Center for Food Safety on the final rule entitled ''Listing of Color Additives Exempt from Certification; Soy Leghemoglobin,'' which published on August 1, 2019. The final rule amended the color additive regulations to provide for the safe use of soy leghemoglobin as a color additive in ground beef analogue products. After reviewing the objections, FDA has

concluded that the objections do not raise issues of material fact that justify a hearing or otherwise provide a basis for revoking the amendment to the regulations. We are also providing notice that the administrative stay of the effective date for this color additive regulation is now lifted.

DATES: The final rule that published in the **Federal Register** of August 1, 2019 (84 FR 37573) with an effective date of September 4, 2019, was administratively stayed by the filing of objections under section 701(e)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 371(e)(2)) as of September 3, 2019. FDA lifts the administrative stay as of December 19, 2019.

ADDRESSES: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number found in brackets in the heading of this final rule into the ''Search'' box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ellen Anderson, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740–3835, 240–402–1309.

SUPPLEMENTARY INFORMATION:

I. Background

In a notification published in the **Federal Register** of December 13, 2018 (83 FR 64045), we announced that we filed a color additive petition (CAP 9C0314) submitted by Impossible Foods, Inc., c/o Exponent, Inc., 1150 Connecticut Avenue NW, Suite 1100, Washington, DC 20036. The petition proposed to amend the color additive regulations in part 73 (21 CFR part 73), ''Listing of Color Additives Exempt from Certification,'' to provide for the safe use of soy leghemoglobin as a color additive in ground beef analogue products such that the amount of soy leghemoglobin protein does not exceed 0.8 percent by weight of the uncooked ground beef analogue product.

Additionally, in the **Federal Register** of August 1, 2019 (84 FR 37573), FDA issued a final rule entitled ''Listing of Color Additives Exempt from Certification; Soy Leghemoglobin,'' amending the color additive regulations to provide for the safe use of soy leghemoglobin in ground beef analogue products. Specifically, the final rule added § 73.520 (21 CFR 73.520), entitled ''Soy leghemoglobin,'' which set forth the identity, specifications, uses and restrictions, labeling, and exemption from batch certification for the color additive. We gave interested persons until September 3, 2019, to file objections and requests for a hearing on the final rule.

II. Objections and Requests for Hearings

Sections 701(e)(2) and 721(d) of the FD&C Act (21 U.S.C. 371(e)(2) and 379e(d)) collectively provide that, within 30 days after publication of an order relating to a color additive regulation, any person adversely affected by such an order may file objections, specifying with particularity the provisions of the order deemed objectionable, stating the grounds therefor, and requesting a public hearing upon such objections. FDA may deny a hearing request if the objections to the regulation do not raise genuine and substantial issues of fact that can be resolved at a hearing (see § 12.24(b)(1) (21 CFR 12.24(b)(1)); see also *Community Nutrition Institute* v. *Young,* 773 F.2d 1356, 1364 (D.C. Cir. 1985)).

Objections and requests for a hearing are governed by part 12 (21 CFR part 12) of FDA's regulations. Under § 12.22(a) (21 CFR 12.22(a)), each objection must meet the following conditions: (1) Must be submitted on or before the 30th day after the date of publication of the final rule; (2) must be separately numbered; (3) must specify with particularity the provision of the regulation or proposed order objected to; (4) must specifically state the provision of the regulation or proposed order on which a hearing is requested (failure to request a hearing on an objection constitutes a waiver of the right to a hearing on that objection); and (5) must include a detailed description and analysis of the factual information to be presented in support of the objection if a hearing is requested (failure to include a description and analysis for an objection constitutes a waiver of the right to a hearing on that objection).

Following the publication of the final rule for the safe use of soy leghemoglobin as a color additive in ground beef analogue products, we received a submission from the Center for Food Safety providing objections and requesting a hearing on each objection. The objections are as follows:

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[ichia] pastoris* yeast protein.'' [1]

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

Objection 4: FDA improperly relied on Impossible Foods' Generally Recognized As Safe (GRAS) Notice 737 instead of independently verifying the safety of soy leghemoglobin for use as a color additive.

Objection 5: FDA should have required separate testing of *P. pastoris* because it is genetically engineered.

Objection 6: FDA violated the National Environmental Policy Act (NEPA) by failing to prepare an environmental assessment or environmental impact statement.

See submission from Jaydee Hanson, Policy Director, and Ryan Talbot, Staff Attorney, Center for Food Safety, to the Dockets Management Staff, Food and Drug Administration, dated September 3, 2019, at pages 1–2, 6–12 (referred to hereinafter as the ''submission'').

III. Standards for Granting a Hearing

Specific criteria for determining whether to grant or deny a request for a hearing are set out in § 12.24(b). Under that regulation, a hearing will be granted if the material submitted by the requester shows, among other things, that: (1) There is a genuine and substantial factual issue for resolution at a hearing (a hearing will not be granted on issues of policy or law); (2) the factual issue can be resolved by available and specifically identified reliable evidence (a hearing will not be granted on the basis of mere allegations or denials or general descriptions of positions and contentions); (3) the data and information submitted, if established at a hearing, would be adequate to justify resolution of the factual issue in the way sought by the requester (a hearing will be denied if the data and information submitted are insufficient to justify the factual determination urged, even if accurate); (4) resolution of the factual issue in the way sought by the person is adequate to justify the action requested (a hearing will not be granted on factual issues that are not determinative with respect to the action requested, *e.g.,* if the action would be the same even if the factual issue were resolved in the way sought); (5) the action requested is not inconsistent with any provision in the

[1] *Pichia pastoris* (*P. pastoris*) is a non-pathogenic and non-toxicogenic strain of yeast that is genetically engineered to express soy leghemoglobin and *P. pastoris* yeast proteins. Soy leghemoglobin protein is the principal coloring agent in the color additive. (See 84 FR 37573 at 37574.)

FD&C Act or any regulation particularizing statutory standards (the proper procedure in those circumstances is for the person requesting the hearing to petition for an amendment or waiver of the regulation involved); and (6) the requirements in other applicable regulations, *e.g.,* 21 CFR 10.20, 12.21, 12.22, 314.200, 514.200, and 601.7(a), and in the notice issuing the final regulation or the notice of opportunity for a hearing are met.

A party seeking a hearing must meet a ''threshold burden of tendering evidence suggesting the need for a hearing'' (*Costle* v. *Pacific Legal Foundation,* 445 U.S. 198, 214–215 (1980), citing *Weinberger* v. *Hynson, Westcott & Dunning, Inc.,* 412 U.S. 609, 620–621 (1973)). An allegation that a hearing is necessary to ''sharpen the issues'' or to ''fully develop the facts'' does not meet this test (*Georgia Pacific Corp.* v. *EPA,* 671 F.2d 1235, 1241 (9th Cir. 1982)). If a hearing request fails to identify any factual evidence that would be the subject of a hearing, there is no point in holding one. In judicial proceedings, a court is authorized to issue summary judgment without an evidentiary hearing whenever it finds that there are no genuine issues of material fact in dispute, and a party is entitled to judgment as a matter of law (see *Rule 56, Federal Rules of Civil Procedure*). The same principle applies to administrative proceedings (see § 12.28).

A hearing request must not only contain evidence, but that evidence should raise a material issue of fact ''concerning which a meaningful hearing might be held'' (*Pineapple Growers Ass'n* v. *FDA,* 673 F.2d 1083, 1085 (9th Cir. 1982)). Where the issues raised in the objection are, even if true, legally insufficient to alter the decision, an Agency need not grant a hearing (see *Dyestuffs and Chemicals, Inc.* v. *Flemming,* 271 F.2d 281, 286 (8th Cir. 1959)). A hearing is justified only if the objections are made in good faith and if they ''draw in question in a material way the underpinnings of the regulation at issue'' (*Pactra Industries* v. *CPSC,* 555 F.2d 677, 684 (9th Cir. 1977)). A hearing need not be held to resolve questions of law or policy (see *Citizens for Allegan County., Inc.* v. *FPC,* 414 F.2d 1125, 1128 (D.C. Cir. 1969); *Sun Oil Co.* v. *FPC,* 256 F.2d 233, 240 (5th Cir. 1958)).

Even if the objections raise material issues of fact, FDA need not grant a hearing if those same issues were adequately raised and considered in an earlier proceeding. Once an issue has been so raised and considered, a party is estopped from raising that same issue in a later proceeding without new evidence. The various judicial doctrines dealing with finality, such as collateral estoppel, can be validly applied to the administrative process (see *Pacific Seafarers, Inc.* v. *Pacific Far East Line, Inc.,* 404 F.2d 804, 809 (D.C. Cir. 1968)). In explaining why these principles ought to apply to an Agency proceeding, the U.S. Court of Appeals for the District of Columbia Circuit wrote: ''The underlying concept is as simple as this: justice requires that a party have a fair chance to present his position. But overall interests of administration do not require or generally contemplate that he will be given more than a fair opportunity'' (*Retail Clerks Union, Local 1401* v. *NLRB,* 463 F.2d 316, 322 (D.C. Cir. 1972); see also *Costle* v. *Pacific Legal Foundation,* 445 U.S. at 215–17).

IV. Analysis of Objections and Response to Hearing Requests

The submission from the Center for Food Safety contains six numbered objections and requests a hearing on each of them. We address each objection below, as well as the evidence and information filed in support of each, comparing each objection and the information submitted in support of it to the standards for granting a hearing in § 12.24(b).

A. Objection 1

The first objection asserts that FDA should not have approved soy leghemoglobin as a color additive to be used in ''. . . *all* ground beef analogue products, not just in plant-based ground beef analogue products'' without additional safety testing and public comment.[2] The objection asserts that Impossible Foods' safety testing of soy leghemoglobin ''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.'' (See page 6 of the submission.) Moreover, the objection claims that the use of soy leghemoglobin in ''all ground beef analogue products requires additional testing for allergenicity.'' (See page 6 of the submission.) The Center for Food Safety provided no scientific data to support its objection.

We clarify that the safety testing conducted by Impossible Foods and described in CAP 9C0314 was not based on the use of the color additive with a soy-based ground beef analogue, as claimed in the objection. The petitioner used a weight-of-evidence approach to address the safety of soy leghemoglobin protein and *P. pastoris* proteins that comprise the color additive. The weight-of-evidence approach, which is a widely used method for assessing protein safety by experts in the scientific community, is based on several elements such as the known function of the protein and its history of exposure, whether the protein is from a toxigenic or allergenic source, the digestibility of the protein, and bioinformatic analysis of the protein to determine if it is structurally similar to known allergens or toxins (*i.e.,* amino acid sequence homology) (Ref 1). In our review of CAP 9C0314, we confirmed that Impossible Foods thoroughly addressed the safety of soy leghemoglobin, including any potential allergenicity, using the weight-of-evidence approach.

Furthermore, we are not aware of any scientific evidence that suggests a food matrix, whether plant-based or animal-based, would modify the structure, function, or safety of soy leghemoglobin under the conditions of its intended use.

The objection failed to include any new information or data that would refute our findings about the safety of soy leghemoglobin in food matrices other than plant-based products. The objection merely alleges that there is a potential for harm, without providing any scientific basis. A hearing will not be granted on the basis of mere allegations or general descriptions of positions and contentions (§ 12.24(b)(2)). The objector must, at a minimum, raise a material issue concerning which a meaningful hearing might be held. Therefore, we are denying the request for a hearing on this objection.

B. Objection 2

The second objection asserts that FDA should require labeling of this color additive as ''soy leghemoglobin/*P. pastoris* yeast protein.'' (See page 6 of the submission.) The Center for Food Safety alleges that the ''labeling approved by FDA does not provide 'sufficient information' about Impossible Foods' product.'' (See page 6 of the submission.) Additionally, the objection states that both soy leghemoglobin and *P. pastoris* proteins should be identified in labeling for consumers who ''believe that they have allergies to either soy products or yeast products.'' (See page 7 of the submission.)

FDA acknowledges that the color additive soy leghemoglobin contains residual amounts of *P. pastoris* yeast

[2] We note that we specifically stated in the final rule, ''For the purposes of this final rule, the term ''ground beef analogue products'' refers to plant-based or other non-animal derived ground beef-like food products.'' See 84 FR 37573. Therefore, if a firm wanted to use soy leghemoglobin as a color additive in animal-derived products, that use would require authorization through the color additive petition process.

protein in addition to the principal coloring component, soy leghemoglobin protein. The allergenicity of soy leghemoglobin protein and residual yeast proteins was addressed in safety studies that included digestibility assays in simulated gastric fluid, bioinformatic analyses, and animal feeding studies. The totality of evidence presented in the color additive petition indicated that there is a reasonable certainty that soy leghemoglobin protein and *P. pastoris* yeast proteins do not pose any unique allergenicity risks when consumed.

Furthermore, under the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA), which added section 403(w) to the FD&C Act (21 U.S.C. 343(w)), the label of a food that contains an ingredient that is or contains protein from a ''major food allergen'' must declare the presence of the allergen in the manner described by the law. As stated in the findings of FALCPA in section 202(2)(A), the major food allergens identified in the FD&C Act account for over 90 percent of all documented food allergies in the United States and represent foods that are likely to result in life-threatening reactions. Because soybeans are identified as a major food allergen, foods that contain soy leghemoglobin must be labeled accordingly. Yeast protein has not been identified as a major food allergen. The objection provided no scientific data on the prevalence or severity of yeast protein allergy to support its objection.

The Center for Food Safety failed to provide any new information or data that would refute our findings about the potential for allergenicity to yeast proteins. The objection merely alleges that there is a potential for harm, without providing any evidence that we have not considered previously. A hearing will not be granted on the basis of mere allegations or general descriptions of positions and contentions (§ 12.24(b)(2)). The objection must, at a minimum, raise a material issue concerning which a meaningful hearing might be held. Therefore, we are denying the request for a hearing on this objection.

C. Objection 3

The third objection asserts that FDA should have required additional testing of the raw color additive product. The objection states, ''[s]ince 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.'' (See page 7 of the submission.) The objection failed to include any new information or data to support this assertion.

We note that the safety studies submitted in support of Impossible Foods' color additive petition for soy leghemoglobin were conducted using ''raw'' soy leghemoglobin preparation. This fact is indicated in the color additive petition as well as in the supporting publications. (See pages 32, 34, and 37 of CAP 9C0314). The Center for Food Safety failed to include any new information or data that would refute our findings about the safety of the ''raw'' soy leghemoglobin preparation, which was considered in our evaluation. A hearing will not be granted on the basis of mere allegations or general descriptions of positions and contentions (§ 12.24(b)(2)). The objector must, at a minimum, raise a material issue concerning which a meaningful hearing might be held. Therefore, we are denying the request for a hearing on this objection.

D. Objection 4

The fourth objection asserts that FDA's reliance on Impossible Foods' GRAS Notice 737 violates the definition of ''safe'' in § 70.3(i) (21 CFR. 70.3(i)). The objection claims ''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 [soy leghemoglobin] for use as a color additive.'' (See page 7 of the submission.) Furthermore, the objection asserts that FDA's reliance on safety studies conducted by Impossible Foods' employees or consultants ''undermines the integrity of the color additive petition process.'' (See page 8 of the submission.)

FDA disagrees with the Center for Food Safety's assertion that our approval of soy leghemoglobin as a color additive in ground beef analogue products is in violation of § 70.3(i), which defines ''safe'' to mean there is convincing evidence that establishes with reasonably certainty that no harm will result from the intended use of the color additive. Impossible Foods submitted CAP 9C0314, a regulatory submission for a color additive petition distinct from GRAS notice 737, seeking approval for the use of soy leghemoglobin as a color additive in ground beef analogue products. FDA acknowledges that the subject of GRAS notice 737, soy leghemoglobin preparation, is the same substance that is the subject of CAP 9C0314. FDA also acknowledges that the safety studies conducted in support of GRAS notice 737 were submitted in support of CAP 9C0314. In addition to evaluating the safety of soy leghemoglobin in response to GRAS notice 737, FDA specifically evaluated its safety as a color additive in response to CAP 9C0314. Furthermore, although the regulatory programs are distinct, the standard of safety—a reasonable certainty of no harm from the intended use—is the same for food additives, color additives, and GRAS substances.

As we stated in the final rule (84 FR 37573 at 37574), our safety evaluation for a color additive considers the additive's manufacturing; its stability; the projected human dietary exposure to the additive and any impurities resulting from the petitioned use of the additive; the additive's toxicological data; and other relevant information (such as published literature) available to us. In establishing that soy leghemoglobin is safe for use as a color additive, we considered the petitioner's weight-of-evidence approach based on: (1) The history of consumption of soy, soy leghemoglobin protein, and *P. pastoris;* (2) the safety of the genetically engineered *P. pastoris* production strain; (3) 14-day and 28-day feeding studies of soy leghemoglobin preparation in rats; (4) mutagenicity and genotoxicity studies of soy leghemoglobin preparation; and (5) an allergenicity assessment of soy leghemoglobin and *P. pastoris* proteins present in the soy leghemoglobin preparation. The objection did not contain any additional information that we did not already consider in our evaluation of the color additive petition, nor did the Center for Food Safety identify any reliable evidence that contradicts FDA's safety determination.

We disagree with the Center for Food Safety's assertion that we must conduct our own safety studies rather than rely on studies conducted or funded by the petitioner to adequately evaluate the safe use of soy leghemoglobin. Studies needed to demonstrate the safety of food ingredients are mostly conducted by the manufacturer or their paid contract laboratories. The FD&C Act and our implementing regulations in 21 CFR parts 70 and 71 do not require us to perform safety studies related to color additives; rather, the burden is on petitioners to provide safety data as part of their petition (21 CFR 71.1). FDA's responsibility is to evaluate the data contained in the petition, as well as other information available to us, to determine if the petitioned use is safe. FDA provides guidance documents (Ref. 2) that specifically describe the type of data that we expect petitioners to generate or rely upon for safety decisions on food ingredients.

We note that the objection criticized two peer-reviewed studies published in

scientific journals because they are co-authored by Impossible Foods' employees and/or their consultants. The utility of such publications is that the journal's peer review process can promote scientific rigor and the entire scientific community can review the studies. This transparency allows others to conduct further studies to test and verify the results and conclusions, if warranted.

FDA disagrees with the Center for Food Safety's assertion that a 90-day feeding study, rather than a 28-day feeding study, with soy leghemoglobin was appropriate because the digestibility studies in simulated gastric fluid showed that the soy leghemoglobin protein and *P. pastoris* proteins were mostly digested in 0.5 minutes and could not be detected beyond 2 minutes under the conditions of the study. These data indicate that both soy leghemoglobin protein and *P. pastoris* proteins are expected to be rapidly digested in the stomach, and these proteins would no longer be available intact following oral administration in either a 28-day or 90-day study. Moreover, sequence analysis of the soy leghemoglobin protein and *P. pastoris* proteins and their known functions suggest that the intact proteins or any fragments thereof are not likely to cause any adverse effects. Therefore, a 90-day study, compared to a 28-day study, has no added utility for demonstrating the safety of this ingredient, as the proteins will be digested rapidly in the stomach just like any other consumed proteins.

Regarding the statistical differences noted in the study and that the objection quotes as ''potentially adverse effects'' (see page 9 of the submission), observed effects that are deemed statistically significant are not necessarily toxicologically relevant. For an observed effect to be toxicologically relevant (*i.e.,* potentially adverse), a clear dose-response should be seen (*e.g.,* increasing the dose of a test substance causes an increase in the observed effect in the test subjects), and the observed effect should occur in both sexes of test species. If the structure and metabolism of the test substance is known, it may be possible to develop a hypothesis on the potential mechanism of adverse effects or lack thereof. The available information on the structure and function of soy leghemoglobin and its fate in the body following consumption do not lend support to the Center for Food Safety's claim that the statistically significant differences reported in the study are indicative of potentially adverse effects in humans.

The objection cites an online report by Robinson and Antoniou (2019)[3] asserting that feeding soy leghemoglobin to rats resulted in statistically significant changes in some clinical chemistry parameters compared to controls. The examples cited are changes in blood chemistry, blood clotting ability, and blood globulin values. The Center for Food Safety surmises that such statistically significant differences could mean potentially adverse effects and are reason for concern. However, differences in observed clinical chemistry parameters, even if statistically significant, do not necessarily mean that treatment-related differences exist. There are numerous accounts of historical control data that demonstrate the extent of inter-animal variability observed in rat strains commonly used in toxicological studies (Refs. 3 to 8). These data show that certain clinical chemistry parameters may have a wide range of normal values in experimental control animals, such that statistical differences seen between control animals and treatment animals due to small changes in the value of the parameter are not likely to be of biological or toxicological significance. Importantly, the changes observed for these parameters in Impossible Food's 28-day study were within historical ranges of control values, did not show a dose-response relationship, and did not occur in both sexes, indicating that the statistically significant differences were incidental and not treatment-related. The objection is based purely on statistical significance and not biological significance or toxicological relevance.

The objection failed to include any new information or data that would refute our conclusion that the data provided in the petition was adequate to establish safety. A hearing will not be granted on the basis of general descriptions of positions and contentions (§ 12.24(b)(2)). The objector must, at a minimum, raise a material issue concerning which a meaningful hearing might be held. Therefore, we are denying the request for a hearing on this objection.

E. Objection 5

The fifth objection asserts that FDA should have required separate testing of *P. pastoris* because it is genetically engineered. The objection states that the use of *P. pastoris* should ''require separate testing for allergenicity as the genetically-engineered yeast proteins are present in the final 'soy leghemoglobin/*P. pastoris* preparation.' '' (See page 9 of the submission.)

Soy leghemoglobin was produced by genetic engineering of *P. pastoris* to express specific and targeted proteins with known functions. The fermentation process used to produce soy leghemoglobin is performed under controlled conditions and good manufacturing practices. Quality control tests are in place to ensure there is no residual *P. pastoris* production strain in the final product. The *P. pastoris* proteins and the soy leghemoglobin protein comprise the final soy leghemoglobin color additive that is the subject of this rulemaking. All safety studies were conducted using the soy leghemoglobin preparation that contained both the soy leghemoglobin protein and the *P. pastoris* proteins. Therefore, the safety of both the soy leghemoglobin protein and the *P. pastoris* proteins were considered in FDA's evaluation. Consequently, there is no scientific basis to conduct additional testing of a *P. pastoris* strain simply because of the methods used to develop the strain. In any event, as previously stated, the studies contained in the color additive petition demonstrated both types of proteins were safe. The objection provided no scientific evidence to support its claim that separate safety testing of the genetically engineered *P. pastoris* yeast is warranted.

The objection failed to include any new information or data to support their contention that separate allergenicity testing is needed for *P. Pastoris* yeast. A hearing will not be granted on the basis of general descriptions of positions and contentions (§ 12.24(b)(2)). The objector must, at a minimum, raise a material issue concerning which a meaningful hearing might be held. Therefore, we are denying the request for a hearing on this objection.

F. Objection 6

The sixth and last objection asserts that FDA violated NEPA by failing to prepare an environmental assessment or environmental impact statement. The objection states that ''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.'' (See page 10 of the submission.) The objection alleges that the use of genetically engineered soybeans as a source of soy protein to formulate ground beef analogues may increase the

[3] Available at: *https://www.gmoscience.org/rat-feeding-studies-suggest-the-impossible-burger-may-not-be-safe-to-eat/*.

use of soybeans derived from genetically engineered soy varieties and compete with the livestock industry for feedstock. (See page 11 of the submission.) Furthermore, the Center for Food Safety suggests that the use of dicamba, a pesticide commonly used on certain crops engineered to be resistant to the pesticide, will increase due to increased reliance on soy protein as an ingredient in the ground beef analogue products. As such, the objection claims that FDA should have considered the potential indirect and cumulative effects of increased pesticide application on genetically engineered soybean crops and should have required an environmental assessment or an environmental impact statement related to CAP 9C0314.

We do not agree that we violated NEPA by failing to prepare an environmental assessment or an environmental impact statement. Furthermore, we do not agree that we failed to consider whether there may be indirect or cumulative adverse effects to threatened and endangered species or their critical habitat resulting from the approval of Impossible Foods' color additive petition that would constitute extraordinary circumstances within the meaning of § 25.21(b) (21 CFR 25.21(b)).

As discussed in the filing notice for the petition (83 FR 64045; December 13, 2018), Impossible Foods claimed that the categorical exclusion in § 25.32(k) (21 CFR 25.32(k)) applied to the proposed use of soy leghemoglobin because the substance 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. Under § 25.21, FDA requires at least an environmental assessment 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. As discussed in the filing notice published in the **Federal Register** of December 13, 2018, Impossible Foods stated that, to their knowledge, no extraordinary circumstances exist regarding the proposed use of soy leghemoglobin. In our analysis of the applicability of the categorical exclusion under § 25.32(k), we focused on soy leghemoglobin production and potential waste products (*i.e.,* food waste and/or excretion products) and identified no extraordinary circumstances related to production, use, or disposal of soy leghemoglobin. In the final rule (84 FR 37573), we stated that we did not receive any new information or comments regarding this claim of categorical exclusion, and therefore determined that the proposed action is categorically excluded under § 25.32(k).

No data or information was provided to support the Center for Food Safety's contention that the approval of soy leghemoglobin as a color additive would result in an increase in the cultivation of genetically engineered soybeans, that such cultivation would lead to an increase in pesticide use such as dicamba, or that such cultivation would result in significant adverse impacts to threatened or endangered species or their critical habitat, requiring the preparation of an environmental assessment or an environmental impact statement. Furthermore, the objection focuses on increased cultivation of genetically engineered soybeans and use of pesticides such as dicamba. The objection does not consider that Impossible Foods' soy leghemoglobin ingredient, the substance that is the subject of the color additive petition, is not grown or derived from genetically engineered soybean plants. Instead, the substance is produced by a strain of genetically engineered yeast; production occurs in vats rather than on a farm and does not require the use of pesticides such as dicamba.

The objection cites a 2019 *Forbes* article [4] as support for the assertion that Impossible Foods ''switch[ed] from wheat to GM soy.'' (See page 11 of the submission.) However, the *Forbes* article discusses the plant-based raw material that forms the burger itself, not the ingredient soy leghemoglobin that is the subject of FDA's action. Thus, the Center for Food Safety's reliance on this article for the proposition that FDA approval of soy leghemoglobin for use as a color additive will lead to an increase in genetically engineered soybean cultivation is misplaced. Because Impossible Foods' soy leghemoglobin ingredient is not derived from genetically engineered soybeans, there is no basis on which to conclude that FDA's approval of soy leghemoglobin for use as a color additive will result in increased cultivation of genetically engineered soybeans and/or an increased use of pesticides in domestic agriculture.[5] To the extent the Center for Food Safety is arguing that FDA's approval of the petition may have an indirect effect on the production of genetically engineered soy by facilitating an overall increase in Impossible Foods' burger production, we note that this argument is speculative and the Center for Food Safety has not identified any evidence that FDA's approval of the petition will have a meaningful effect of this nature.

The objection failed to include any new information or data that would change our findings with respect to the applicability of the categorical exclusion in § 25.32(k). The request for a hearing does not provide any evidence to support its claims. A hearing will not be granted on the basis of mere allegations or general descriptions of positions and contentions (§ 12.24(b)(2)). The objections must, at a minimum, raise a material issue concerning which a meaningful hearing might be held. Therefore, we are denying the request for a hearing on this objection.

V. Summary and Conclusions

Section 721 of the FD&C Act requires that a color additive be shown to be safe prior to marketing. Under § 70.3(i), a color additive is safe if there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use. In the final rule authorizing the use of soy leghemoglobin, we concluded that the data presented by the petitioner demonstrate that soy leghemoglobin is safe for its intended use in ground beef analogue products.

The petitioner has the burden to demonstrate the safety of the additive to gain FDA approval. Once we make a finding of safety, the burden shifts to an objector, who must come forward with evidence that calls into question our conclusion (see section 701(e)(2) of the FD&C Act).

Despite its allegations, the Center for Food Safety has not established that we have overlooked significant information contained within the record in reaching our conclusion that the use of soy leghemoglobin in ground beef analogue products is safe. In such circumstances, we have determined that the objections do not raise any genuine and substantial issue of fact that can be resolved by an evidentiary hearing (§ 12.24(b)). Accordingly, we are denying the requests for a hearing. Furthermore, after evaluating the objections, we have concluded that the objections do not provide any basis for us to reconsider our decision to issue the final rule authorizing the use of soy leghemoglobin in ground beef analogue products. Accordingly, we are not

[4] Available at: *https://www.forbes.com/sites/louisaburwoodtaylor/2019/07/31/impossible-in-full-scale-up-mode-with-new-burger-manufacturing-deal--fda-approval/.*

[5] We note that, based on publicly available information from the United States Department of Agriculture, approximately 94 percent of the soybean acres planted in 2019 in the United States were genetically engineered varieties (*https://www.ers.usda.gov/topics/farm-practices-management/biotechnology/*).

making any changes in response to the objections.

The filing of the objections served to stay automatically the effectiveness of § 73.520. Section 701(e)(2) of the FD&C Act states that, until final action upon such objections is taken by the Secretary, the filing of such objections operates to stay the effectiveness of those provisions of the order to which the objections are made. Section 701(e)(3) of the FD&C Act further stipulates that, as soon as practicable, the Secretary shall by order act upon such objections and make such order public. We have completed our evaluation of the objections and conclude that a continuation of the stay of § 73.520 is not warranted.

In the absence of any other objections and requests for a hearing, we conclude that this document constitutes final action on the objections received in response to the regulation as prescribed in section 701(e)(2) of the FD&C Act. Therefore, we are ending the administrative stay of the regulation as of December 19, 2019 for the § 73.520 listing soy leghemoglobin as a color additive for use in ground beef analogue products.

VI. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. Ladics, G.S., ''Current Codex Guidelines for Assessment of Potential Protein Allergenicity.'' *Food and Chemical Toxicology,* 46: S20–S23, 2008.
2. *FDA. ''Redbook 2000 Guidance for Industry and Other Stakeholders; Toxicological Principles for the Safety Assessment of Food Ingredients,'' 2007. Retrieved from *https://www.fda.gov/media/79074/download.*
3. Giknis, M.L.A. and C.B. Clifford, ''Clinical Laboratory Parameters for Crl:CD(SD) Rats,'' 2006. Retrieved from *https://www.crj.co.jp/cms/pdf/info_common/50/8250933/rm_rm_r_clinical_parameters_cd_rat_06.pdf.*
4. Giknis, M.L.A. and C.B. Clifford, ''Clinical Laboratory Parameters for Crl:WI(Han),'' 2008. Retrieved from *https://www.criver.com/sites/default/files/resources/rm_rm_r_Wistar_Han_clin_lab_parameters_08.pdf.*
5. Matsuzawa, T., M. Nomura, and T. Unno, ''Clinical Pathology Reference Ranges of Laboratory Animals. Working Group II, Nonclinical Safety Evaluation Subcommittee of the Japan Pharmaceutical Manufacturers Association.'' *Journal of Veterinary Medical Science,* 55(3): 351–362, 1993.
6. Pettersen, J.C., R.L. Morrissey, D. R. Saunders, et al., ''A 2-Year Comparison Study of Crl:CD BR and Hsd:Sprague-Dawley SD Rats.'' *Fundamental and Applied Toxicology,* 33: 196–211, 1996.
7. Petterino, C. and A. Argentino-Storino, ''Clinical Chemistry and Haematology Historical Data in Control Sprague-Dawley Rats From Pre-clinical Toxicity Studies.'' *Experimental and Toxicologic Pathology,* 57: 213–219, 2006.
8. Seibel, J., K. Bodié, S. Weber, et al., ''Comparison of Haematology, Coagulation and Clinical Chemistry Parameters in Blood Samples From the Sublingual Vein and Vena Cava in Sprague-Dawley Rats.'' *Laboratory Animals,* 44: 344–351, 2010.

List of Subjects in 21 CFR Part 73

Color additives, Cosmetics, Drugs, Foods, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e) and under authority delegated to the Commissioner of Food and Drugs (section 1410.10 of the FDA Staff Manual Guide), notice is given that the objections and requests for hearings were filed in response to the August 1, 2019, final rule. Notice is also given that FDA is denying these objections and requests for hearings. Accordingly, the administrative stay on the effective date of the amendments is lifted as of December 19, 2019.

Dated: December 12, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–27173 Filed 12–17–19; 11:15 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 282

[EPA–R01–UST–2019–0421; FRL–10003–06–Region 1]

New Hampshire: Final Approval of State Underground Storage Tank Program Revisions, Codification, and Incorporation by Reference

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule; correction.

SUMMARY: The Environmental Protection Agency (EPA) is correcting a direct final rule that appeared in the **Federal Register** on November 1, 2019. The document is taking direct final action to approve revisions to the State of New Hampshire's Underground Storage Tank (UST) program submitted by the New Hampshire Department of Environmental Services (NHDES). This action also codifies EPA's approval of New Hampshire's state program and incorporates by reference those provisions of the State regulations that meet the requirements for approval.

DATES: This rule is effective December 31, 2019, unless EPA received adverse comment by December 2, 2019. If EPA received adverse comments, it will publish a timely withdrawal in the **Federal Register** informing the public that the rule will not take effect. The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register, as of December 31, 2019, in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

FOR FURTHER INFORMATION CONTACT: Susan Hanamoto, RCRA Waste Management, UST, and Pesticides Section; Land, Chemicals, and Redevelopment Division; EPA Region 1, 5 Post Office Square, Suite 100, (Mail Code 07–1), Boston, MA 02109–3912.

SUPPLEMENTARY INFORMATION: In FR Doc. 2019–23709 appearing on pages 58627 and 58631 in the **Federal Register** of Friday, November 1, 2019, the following corrections are made:

1. On page 58627, in the heading of the document, the agency heading is corrected to read ''ENVIRONMENTAL PROTECTION AGENCY'' and in the AGENCY caption, the agency is corrected to read ''Environmental Protection Agency (EPA)''.

2. On page 58627, in the first sentence of the SUMMARY, ''Environmental Services Agency'' is corrected to read ''Environmental Protection Agency''.

3. On page 58631, middle column, in the List of Subjects in 40 CFR part 282, ''Environmental Services'' is corrected to read ''Environmental Protection''.

Dated: November 5, 2019.

Nancy Barmakian,

Acting Director of Land, Chemicals, and Redevelopment Division.

[FR Doc. 2019–26690 Filed 12–18–19; 8:45 am]

BILLING CODE 6560–50–P