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News Alert

FDA Food Chemical Regulation After the MAHA Executive Order

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Just before the change in administration, the Food and Drug Administration (FDA) made headlines by revoking approvals to use the color additive FD&C Red Dye No. 3 in food after January 15, 2027. This was the latest example of FDA regulating—including banning—chemicals in food. Now FDA is moving towards banning two more food dyes and phasing out six others.

FDA has long regulated chemicals used in food, drugs, and cosmetics under the Federal Food, Drug, and Cosmetic Act (FFDCA). While the new administration generally disfavors new regulations or market controls, its recent establishment of the Make America Healthy Again (MAHA) Commission suggests that FDA will be active in repealing other longstanding food chemical approvals, and thus increasing regulation, assuming it has the staff resources to do so and the scientific basis for such moves to survive legal challenge. Manufacturers and other stakeholders should understand FDA's general approach to food chemical regulation and monitor FDA efforts to revoke previous approvals or otherwise increase scrutiny over the use of individual substances.

What Are Food and Color Additives?

Food Additives

By default, essentially any substance added to food with the intent of becoming part of that food, or to affect its characteristic (other than color), is a food additive and therefore presumed unsafe. There are exceptions where the manufacturer secures FDA clearance through a food additive petition or FDA reviews a food contact notification demonstrating a reasonable certainty of no harm under the intended conditions of use. FFDCA §§ 201(s), 409(a). Substances generally recognized as safe (GRAS) are not considered food additives, nor are substances only in foods at de minimis levels (below the "threshold of regulation").

Color Additives

Colorants occupy their own narrower lanes. Every dye, pigment, or other substance used primarily to impart color requires a full-color additive petition with no GRAS or threshold of regulation escape hatches. FFDCA §§ 201(t), 721(a). Synthetic dyes must also pass batch-by-batch certification under 21 C.F.R. Part 80.

What Is MAHA?

On February 13, President Trump issued Executive Order 14212, "Establishing the President's Make America Healthy Again Commission." Among other things, the order set up an inter-agency body chaired by the Secretary of Health and Human Services (HHS), Robert F. Kennedy, Jr., which is mandated to prepare an assessment by May 24 on topics including "the threat that potential over-utilization of … certain food ingredients … pose to children with respect to chronic inflammation or other established mechanisms of disease." The commission must then submit a strategy for achieving the listed goals.

Secretary Kennedy took his first public step to implement the MAHA executive order with regard to food and color additives on March 10, when he directed FDA to consider removing the current self-affirmation pathway for determining that a food ingredient is GRAS. See our previous alert on the topic here.

According to press reports, Secretary Kennedy told food industry leaders in a closed-door meeting on March 10, that he wants them to remove artificial color additives from their products by the end of his time in office.

On March 20, Secretary Kennedy announced the availability of a Chemical Contaminants Transparency Tool. The tool provides information on food-based contaminant levels in one convenient location. Contaminant levels listed in the tool includes; tolerances, action levels, guidance levels, derived intervention levels, recommended maximum levels, and advisory levels.

What's Next for Artificial Color Additives Used in Food?

On April 22, FDA announced that it will take the following actions:

1. Establishing a national standard and timeline for the food industry to transition from petrochemical-based dyes to natural alternatives.
2. Initiating the process to revoke authorization for two synthetic food colorings—Citrus Red No. 2 and Orange B—within the coming months.
3. Working with industry to eliminate six remaining synthetic dyes—FD&C Green No. 3, FD&C Red No. 40, FD&C Yellow No. 5, FD&C Yellow No. 6, FD&C Blue No. 1, and FD&C Blue No. 2—from the food supply by the end of next year.
4. Authorizing four new natural color additives in the coming weeks, while also accelerating the review and approval of others.
5. Partnering with the National Institutes of Health (NIH) to conduct comprehensive research on how food additives impact children's health and development.
6. Requesting food companies to remove FD&C Red No. 3 sooner than the 2027-2028 deadline previously required.

In response, the International Dairy Foods Association announced its Healthy Dairy in Schools Commitment, a voluntary effort to eliminate the use of certified artificial colors Red 3, Red 40, Green 3, Blue 1, Blue 2, Yellow 5, and Yellow 6 in all milk, cheese, and yogurt products sold to K-12 schools for use in the National School Lunch Program and/or School Breakfast Program by the start of the 2026-2027 school year.

The eight color additives now at issue at FDA are:

- FD&C Red No. 40 (used in processed foods and medications)
- FD&C Yellow No. 5 (used in processed foods)
- FD&C Yellow No. 6 (used in processed foods, medications, and cosmetics)
- FD&C Blue No. 1 (used in processed foods, medications, dietary supplements and cosmetics)
- FD&C Blue No. 2 (used in processed foods, medications, dietary supplements and cosmetics)
- FD&C Green No. 3 (used in processed foods)
- Orange B (used solely in hot dog and other sausage casings)
- Citrus Red No. 2 (used solely to brighten orange peels)

For more information, see this FDA report from 2016.

Additionally, some states recently moved to ban these color additives. In 2024, California banned Red No. 40, Yellow No. 5, Yellow No. 6, Blue No. 1, Blue No. 2, and Green No. 3 (the state had already banned Red No. 3) from school lunches beginning December 31, 2027. West Virginia recently banned these same color additives (including Red No. 3) from school lunches starting August 1, 2025, and from food sold in the state beginning January 1, 2027. These state bans were implemented through legislation, rather than through a science-based review process, such as that required of FDA to withdraw approvals for color additives.

In a statement issued in response to the April 22 announcement, the Consumer Brands Association praised FDA and HHS for "reassert[ing] their leadership in response to the myriad of state activity in the food regulation space. A state patchwork of differing laws creates confusion for consumers, limits access to everyday goods, deters innovation, and increases costs at the grocery store."

What Other Food Chemicals Might FDA Pursue?

FDA posted a list of select chemicals in the food supply that are under review. The list includes, among others, propylparaben, potassium bromate, and some food additives that are the subject of petitions (see below). This list may provide candidates for MAHA action.

In 2024, FDA developed a systematic process for post-market assessment of chemicals in food, including food additives, color additives, and contaminants. In September, FDA held a public meeting to hear stakeholder perspectives on the process. The new administration may use this process to identify candidate food additive and/or color additive approvals for possible amendment, revocation, or phase-out.

FDA might also act on earlier petitions to revoke its approvals for the use of certain chemicals in food. The FDA website lists Food Additive and Color Additive Petitions Under Review or Held in Abeyance. While many of the petitions are from industry asking for FDA approval of food chemicals, some are by NGOs or private citizens that ask FDA to revoke approvals of certain chemicals used in food(a 2023 petition by several NGOs led to the recent ban on Red Dye No. 3).

Pending petitions include:

- **Titanium dioxide**
  - Color Additive Petition CAP 3C0325. Petition to revoke the color additive listing for use of titanium dioxide in food. The petition, filed March 13, 2023, asks FDA to remove its approval of use of synthetically-prepared titanium dioxide in coloring food, 21 C.F.R. § 73.575.
- **Methylene chloride, trichloroethylene, and ethylene dichloride**
  - Color Additive Petition CAP 4C0327. Petition to amend the color additive regulations to remove the solvents ethylene dichloride, methylene chloride, and trichloroethylene as permitted diluents in color additive mixtures for food use exempt from certification. The petition, filed November 6, 2023, asks FDA to amend 21 C.F.R. §§ 73.1, diluents in color additive mixtures for food use exempt from certification; 73.30, annatto extract; 73.345, paprika oleoresin; and 73.615, turmeric oleoresin, and to remove the permitted use of ethylene dichloride, ethylene chloride, and trichloroethylene. The petition also asks FDA to amend 21 C.F.R. §§ 73.1, 73.30, 73.345, and 73.615 to remove ethylene dichloride, methylene chloride, and trichloroethylene as permitted solvents for the extraction of those color additives.
- **Methylene chloride, trichloroethylene, ethylene dichloride, and benzene**
  - Food Additive Petition FAP 4A4839. Petition to amend the food additive regulations to remove the solvents benzene, ethylene dichloride, methylene chloride, and trichloroethylene. The petition, filed December 21, 2023, asks FDA to amend 21 C.F.R. §§ 172.560, 172.710, 173.230, 173.255, 173.290, and 173.315 to remove approval of those solvents to produce food and food ingredients.
- **BPA**
  - Food Additive Petition FAP 2B4831. Petition to amend the food additive regulations to remove or restrict authorizations for the use of bisphenol A (BPA). The petition, filed April 7, 2022, asks FDA to amend the food additive regulations in 21 C.F.R. §§ 175.105, 175.300, 177.1440, 177.1580, 177.1585, 177.2280, and 177.2440 to remove authorizations for the use of BPA; to establish a migration limit for BPA from the authorized uses of BPA in food contact articles in §§ 177.1440, 177.1580, 177.1585, and 177.2280; and to add a new provision to part 174 with a restriction on the use of BPA, stating that the substance is subject to a specific migration limit of 0.5 nanograms per kilogram of food.
- **PFAS in polyethylene**
  - Food Additive Petition FAP 3B4837. Petition to amend the food additive regulations to remove authorization of fluorinated polyethylene in food packaging. The petition, filed April 17, 2024, asks FDA to remove its approval of the use of fluorinated polyethylene as an indirect food additive at 21 C.F.R. § 177.1615.
- **PFAS in foods**
  - Citizen Petition Docket No. FDA-2023-P-4826-0001. Petition to request tolerance-setting for certain PFAS substances. The petition, filed December 1, 2023, asks FDA to establish tolerances at the method detection limit (0.05 ppb for residues of either 26 or 30 PFAS in a variety of foods. On January 24, 2025, the petitioner filed a complaint in federal court alleging unreasonable delay in responding to the petition. *Tucson Environmental Justice*

Task Force v. FDA, No. 4:25-cv-00035-JAS (D. Ariz.). On March 21, the court ordered the case to be continued until either FDA issues a final decision on the petition or December 31, 2025, whichever is earlier.

- **BHA**
  - Food Additive Petition FAP 0A4216. Petitions to prohibit the use of butylated hydroxyanisole (BHA) as an antioxidant in food. The petitions (a food additive petition and a citizen petition), filed June 22, 1990, ask FDA to amend the food additive regulations, GRAS regulations, and the prior sanction regulations to prohibit the use of BHA in food. The petitions have been pending for almost 35 years, but FDA still lists them as being under review.

Some of these petitions are already encountering political headwinds. For example, in response to a NGO petition to "Make America Healthy Again" by tightening regulation of certain pesticide residues on food, 79 U.S. Senators and members of congress recently sent a letter to the heads of HHS, the U.S. Department of Agriculture, and EPA noting their concerns that "environmental activists … are seeking to influence the work of the [MAHA] Commission" and push for bans of "safe, well-regulated agricultural inputs" and various food ingredients, such as plant-based oils.

What Must FDA Do to Revoke Food Additive and Color Additive Approvals?

As noted above, each food additive and color additive must receive FDA approval as safe, meaning that there is a reasonable certainty that the additive will not cause harm under its intended conditions of use.

Some approvals may be longstanding and have been based on evidence that no longer reflects the state of the science today. From time to time, FDA reexamines the data supporting certain food or color additive regulations, often in response to petitions to amend or revoke those regulations. For example, besides revoking approval for use of Red Dye No. 3 in food in 2025, FDA removed its approval of brominated vegetable oil in food in 2024, and in 2023 it revised its regulations to provide that partially hydrogenated vegetable oils are not GRAS.

Following the same procedures as for its initial approval of a food or color additive, FDA must make a science-based decision about safety before amending or revoking regulations authorizing such additives' use in food.

Section 409(i) of the FFDCA addresses the procedure by which FDA may amend or repeal food additive regulations, or to declare food contact notifications ineffective. That procedure must follow the same procedures specified for adopting those regulations. Under 21 C.F.R. § 171.130, FDA may propose amending or repealing a regulation pertaining to a food additive. to do so, petitions to FDA must show, for example, that new data is available regarding the toxicity of the chemical, or that experience with the existing regulation or exemption may justify its amendment or repeal. Sufficient evidence that a food additive causes cancer will lead FDA to revoke its authorization per the food additive Delaney Clause, section 409(c)(3). Under sections 409(f) and (g), once FDA issues an order repealing a food additive regulation, any aggrieved person may file objections, request a public hearing, and ultimately seek judicial review.

One option allowing FDA to repeal a food additive regulation is receipt of a petition establishing that "old uses" of that additive have been abandoned. 21 C.F.R. § 171.130(b). An amendment or revocation based

on abandonment is not based on safety, but is based on the fact that regulatory authorization is no longer necessary because the use of that food additive has been completely or partially and permanently abandoned. An abandonment petition opens the door to industry ceasing to use a controversial food additive without a risk-based finding. An FDA listing of final food additive and color additive rules identifies six rulemakings where FDA revoked food additive regulations based on petitions indicating abandonment, including for 25 plasticizers and two PFAS used as oil and water repellants.

Section 721(d) of the FFDCA provides how FDA may issue an order to adopt, amend, or revoke a color additive regulation. 21 U.S.C. § 379e(d). FDA must weigh considerations such as the additive's probable consumption, cumulative effect, safety factors, and whether analytical techniques are available. For FDA to grant a petition that seeks repeal of a color additive regulation based upon new data concerning the safety of the color additive, the data must be adequate for FDA to conclude that there is no longer a reasonable certainty of no harm from the intended use of the color additive. Alternatively, FDA would have to find the additive is unsafe under the color additive Delaney Clause, section 721(b)(5)(B), because it causes cancer. The petitioner or any aggrieved person may request referral to an advisory committee and ultimately seek judicial review.

Who at FDA Will Lead Efforts to Review Food and Color Additive Regulations?

Dr. Martin Makary was confirmed by the Senate as FDA Commissioner on March 25, 2025. His background is in medicine, suggesting expertise with respect to drug and medical device regulation, rather than food safety specifically.

In June 2024, FDA announced its reorganization, with implementation beginning on October 1, 2024. Among other changes, its Center for Food Safety and Applied Nutrition (CFSAN) became the new Human Foods Program (HFP). The Acting Deputy Commissioner for Human Foods is Kyle Diamantas, J.D. The Principal Deputy Director for Human Foods is Dr. Donald A. Prater, who was formerly Acting Director of CFSAN.

Within HFP is the new Office of Food Chemical Safety, Dietary Supplements, and Innovation (also referred to as the Chemical Safety Office), which is tasked with ensuring that the chemicals in food (whether added purposefully or as contaminants) are safe. The office's director is Mark Hartman, who, until December 2024, was the Deputy Director of EPA's Office of Pollution Prevention and Toxics (OPPT) and worked full-time on TSCA. He brings years of experience to FDA's Chemical Safety Office in evaluating the safety of chemicals for uses not subject to the FFDCA (TSCA does not apply to chemicals subject to the FFDCA).

Color additives are regulated by the Office of Cosmetics and Colors (OCAC), which is in the Office of the Chief Scientist. The Acting Chief Scientist is Dr. Steven Kozlowski, who has a background in drug development at FDA. The Acting Director of OCAC is Prashiela Manga, Ph.D., who was previously the Deputy Director of OCAC.

Staff layoffs at FDA may make it difficult for that agency to revoke approvals for the use of the food additives and/or color additives that may be targeted in the upcoming MAHA Commission report, even to support the MAHA agenda. On April 10, Secretary Kennedy announced that about 10,000 employees of HHS had left voluntarily, and the agency expected to lay off another 10,000, reducing the department's full-time staff by about 25%. He did not specify the impacts on FDA, but press reports indicate that the agency will lose about 3,500 positions. Further, FDA may be folded into a new Administration for a Healthy America, dedicated to disease prevention and fighting chronic disease.

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