



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 73

[Docket No. FDA-2026-C-3071]

#### Filing of Color Additive Petition from the International Association of Color

#### Manufacturers; Request to Amend the Color Additive Regulations to Remove the Solvents

#### Methylene Chloride, Trichloroethylene, and Ethylene Dichloride

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notification of petition.

**SUMMARY:** The Food and Drug Administration (FDA or we) is announcing that we have filed a color additive petition, submitted by the International Association of Color Manufacturers (IACM or petitioner), proposing that we amend the color additive regulations to no longer provide for the use of three specified solvents (methylene chloride, trichloroethylene, and ethylene dichloride) for preparing certain color additives because these uses have been permanently abandoned.

**DATES:** The color additive petition was filed on March 20, 2026. Submit either electronic or written comments by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

*Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comment, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### *Written/Paper Submissions*

Submit written/paper instructions as follows:

- Mail/Hand Delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA-2026-C-3071 for "Filing of Color Additive Petition from the International Association of Color Manufacturers; Request to Amend the Color Additive Regulations to Remove the Solvents Methylene Chloride, Trichloroethylene, and Ethylene Dichloride." Received comments, those filed in a timely

manner (see ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comment only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:

<https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

**FOR FURTHER INFORMATION CONTACT:** Daniel Hlavaty, Office of Food Chemical Safety, Dietary Supplements, and Innovation, Human Foods Program, Food and Drug

Administration, 5001 Campus Dr., College Park, MD 20740, 301-796-1481; or Alexandra Beliveau, Office of Policy and International Engagement, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2378.

## **SUPPLEMENTARY INFORMATION:**

### I. Background

Under section 721(d)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 379e(d)(1)), we are giving notice that we have filed a color additive petition (CAP 5C0340), submitted by IACM, 1101 17th St NW Suite 700, Washington, DC 20036. The petition proposes that we amend §§ 73.30 (21 CFR 73.30, “Annatto extract”), 73.345 (21 CFR 73.345, “Paprika oleoresin”), and 73.615 (21 CFR 73.615, “Turmeric oleoresin”) to remove methylene chloride, trichloroethylene, and ethylene dichloride as permitted extraction solvents for the manufacture of annatto extract, paprika oleoresin, and turmeric oleoresin for use as exempt color additives in food. The petition further proposes that we amend § 73.1 (21 CFR 73.1, “Diluents in color additive mixtures for food use exempt from certification”) to remove methylene chloride as a permitted diluent in color additive mixtures in inks for marking fruits and vegetables. The petition requests that we make these amendments on the basis that these uses of the solvents have been permanently abandoned.

The substances that are the subject of this petition and their corresponding Chemical Abstracts Service (CAS) numbers are:

1. Methylene chloride (CAS No. 75-09-2);
2. Trichloroethylene (CAS No. 79-01-6); and
3. Ethylene dichloride (CAS No. 107-06-2).

The petition identifies §§ 73.1030 (21 CFR 73.1030, “Annatto extract”) and 73.2030 (21 CFR 73.2030, “Annatto”) as also being impacted by this petition. Although the regulations in §§ 73.1030 and 73.2030 do not directly refer to methylene chloride, trichloroethylene, or ethylene dichloride, the regulations authorize their use by cross-referencing § 73.30(a)(1). Therefore,

while the petition's request would not amend the codified language in § 73.1030 or 73.2030, amending § 73.30(a)(1) to remove methylene chloride, trichloroethylene, and ethylene dichloride as permitted extraction solvents for the manufacture of annatto extract used in coloring foods (§ 73.30) would result in the removal of methylene chloride, trichloroethylene, and ethylene dichloride as permitted extraction solvents for the manufacture of annatto extract used in coloring drugs (§ 73.1030) and annatto used in coloring cosmetics (§ 73.2030).

## II. Abandonment

The FD&C Act authorizes us to regulate “color additives” (see section 721(b) of the FD&C Act (21 U.S.C. 379e(b))). The FD&C Act defines “color additive,” in relevant part, as a material which 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, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with another substance) of imparting color (see section 201(t) of the FD&C Act (21 U.S.C. 321(t))). Color additives used in or on a food, drug, certain medical devices, or cosmetics are deemed unsafe and prohibited except to the extent that we approve their use through issuance of a regulation (see section 721(a) of the FD&C Act).

The FD&C Act provides a process through which any person who wishes to use a color additive in or on food, drugs, certain medical devices, or cosmetics, may submit a petition proposing the issuance of a color additive regulation listing such use with supporting information. In response to a color additive petition, FDA may issue a regulation listing a color additive for use in or on food, drugs, certain medical devices, or cosmetics only if it determines that the additive is suitable and safe for such use (see section 721(b)(2)(A) of the FD&C Act). A color additive petition may also be submitted to propose the amendment or repeal of an existing color additive regulation (see section 721(b)(5)(C) and (d) of the FD&C Act).

Section 701(e) through (g) of the FD&C Act (21 U.S.C. 371(e) through (g)) applies to the issuance, amendment, or repeal of color additive regulations (see section 721(d) of the FD&C Act). Section 701(e) of the FD&C Act provides that any action for the issuance, amendment, or repeal of a color additive regulation may be initiated by a proposal made by the Secretary or by a petition of any interested persons showing reasonable grounds. It further requires that FDA publish such a proposal, provide an opportunity for all interested persons to present their views, and then by order act upon such proposal.

As support for the assertion that the uses of methylene chloride, trichloroethylene, and ethylene dichloride in the manufacture of annatto extract and annatto, paprika oleoresin, and turmeric oleoresin have been abandoned, the petition includes a summary of the results of a survey that IACM sent to its members and other non-member firms. The petitioner describes IACM members as comprising a meaningful proportion of the current global color industry representing manufacturers and users of color additives. The other non-member firms that IACM surveyed included members of the American Spice Trade Association, the Flavor and Extract Manufacturers Association, and the Natural Food Colors Association, and independent firms, to cover the total U.S. market and support their conclusion that the uses of these substances have been permanently abandoned.

The petitioner asked the recipients to verify that they do not:

- Currently manufacture, purchase, use, or import annatto extract (§ 73.30), turmeric oleoresin (§ 73.615), and/or paprika oleoresin (§ 73.345) for color additive use using methylene chloride, trichloroethylene, and/or ethylene dichloride as extraction solvents whether individually or in combination;
- Intend to manufacture or import for use in food in the United States the color additives annatto extract (§ 73.30), paprika oleoresin (§ 73.345) or turmeric oleoresin (§ 73.615) using methylene chloride, trichloroethylene, or ethylene dichloride whether individually or in combination as extraction solvents; and

- Currently maintain any inventory of the color additives annatto extract (§ 73.30), paprika oleoresin (§ 73.345) or turmeric oleoresin (§ 73.615) that were manufactured using methylene chloride, trichloroethylene, or ethylene dichloride whether individually or in combination as extraction solvents which will be used in food in the United States.

In its summary of the survey results, the petitioner stated that the survey included 44 unique companies and 3 trade associations that collectively represent an additional 375 companies. All the companies that participated in the survey confirmed that they have abandoned methylene chloride, trichloroethylene, and ethylene dichloride for use in the manufacture of annatto extract (§ 73.30), paprika oleoresin (§ 73.345), and turmeric oleoresin (§ 73.615).

With respect to § 73.30, while the petitioner's survey focused on the use of methylene chloride, trichloroethylene, and/or ethylene dichloride as extraction solvents to manufacture annatto extract as specified in § 73.30, the petitioner asserts that the color industry manufactures the colors according to the specifications in FDA's color additive regulations, without consideration of end use. Therefore, the petitioner asserts that since the survey confirmed that methylene chloride, trichloroethylene, and ethylene dichloride have been abandoned in the U.S. for the manufacturing, purchasing, use, or import of annatto extract as specified in § 73.30, the abandonment of the use of these solvents to manufacture annatto extract applies not only to use of the solvents to manufacture annatto extract used in coloring foods (§ 73.30), but also to the use of the solvents to manufacture annatto extract used in coloring drugs (§ 73.1030) and annatto used in coloring cosmetics (§ 73.2030).

As support for the assertion that the use of methylene chloride as a diluent in color additive mixtures in inks for marking fruit and vegetables has been abandoned, the petitioner engaged in discussions with both the International Fresh Produce Association (IFPA), which represents the full fresh produce supply chain, and the National Association of Printing Ink Manufacturers (NAPIM), which represents 85 percent of domestic ink manufacturing. The

petitioner found that the use of inks for marking fruit and vegetables is limited and that no chlorinated organics are used in production ink systems or the manufacturing process. IACM received confirmation from NAPIM that NAPIM's members do not manufacture nor market their products for marking fruits and vegetables. IACM also confirmed with IFPA that IFPA's members do not:

- Currently manufacture for use in food in the United States inks for marking fruit and vegetables (§ 73.1(b)(1)(ii)) using methylene chloride as a diluent;
- Currently import for use in food in the United States inks for marking fruit and vegetables (§ 73.1(b)(1)(ii)) using methylene chloride as a diluent;
- Intend to manufacture or import for use in food in the United States inks for marking fruit and vegetables (§ 73.1(b)(1)(ii)) using methylene chloride as a diluent; and
- Currently maintain any inventory of inks for marking fruit and vegetables (§ 73.1(b)(ii)) using methylene chloride as a diluent which will be used in food in the United States.

We specifically seek comments regarding IACM's petition to amend §§ 73.1, 73.30 (which is cross-referenced in §§ 73.1030 and 73.2030), 73.345, and 73.615 of the color additive regulations to no longer allow the use of methylene chloride, trichloroethylene, and ethylene dichloride in the specified applications because these uses in the manufacture of color additives have been abandoned. Accordingly, we request comments that address whether the uses of these substances in the identified applications have been abandoned. For example, we request information regarding whether annatto extract, paprika oleoresin, or turmeric oleoresin manufactured using these substances or inks for marking fruit and vegetables using methylene chloride are currently being introduced or delivered for introduction into the U.S. market for use as color additives in foods (and with respect to annatto extract and annatto, for use in drugs and cosmetics, respectively). Any comments indicating that the specified uses of one or more of the substances have not been abandoned should specify the substance(s), the specific use(s), any

relevant regulation(s) authorizing the use, and a description of the product that contains the substance(s).

We are currently unaware of information demonstrating the continued use of these substances in the manufacture of the color additive uses listed. We are providing the public 60 days to submit comments. We anticipate that some interested persons may wish to provide us with certain information they consider to be trade secret or confidential commercial information (CCI) under Exemption 4 of the Freedom of Information Act (5 U.S.C. 552). Interested persons may claim information that is submitted to us as CCI or trade secret by clearly marking both the document and the specific information as “confidential.” Information so marked will not be disclosed except in accordance with the Freedom of Information Act and our disclosure regulations (21 CFR part 20). Interested persons must also submit a copy of the comment that does not contain the information claimed as confidential for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice.

We are not requesting comments on the safety of these uses of the substances in the manufacture of these color additives because such information is not relevant to abandonment, which is the basis of the proposed action. We will not consider any comments addressing safety in our evaluation of this petition.

The petition is available in the docket. We invite comments, additional data, and other information related to the issues raised by this petition. If we determine that the available data justify amending §§ 73.30 (which is cross-referenced in §§ 73.1030 and 73.2030), 73.345, and 73.615 to no longer provide for use of the three specified substances in the manufacture of annatto extract, paprika oleoresin, and turmeric oleoresin, respectively, and amending § 73.1 to no longer provide for the use of methylene chloride as a diluent in color additive mixtures in inks for marking fruit and vegetables, we will publish our decision in the *Federal Register* in accordance with 21 CFR 71.20.

The petitioner has claimed that this action is categorically excluded under 21 CFR 25.32(m), which applies to an action to prohibit or otherwise restrict or reduce the use of a substance in food, food packaging, or cosmetics. In addition, the petitioner has stated that, to their knowledge, no extraordinary circumstances exist (see 21 CFR 25.21). If FDA determines a categorical exclusion applies, neither an environmental assessment nor an environmental impact statement is required. If FDA determines a categorical exclusion does not apply, we will request an environmental assessment and make it available for public inspection.

**Grace R. Graham,**

*Deputy Commissioner for Policy, Legislation, and International Affairs.*

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