This document is scheduled to be published in the Federal Register on 2026-11-10 and available online at **https://www.federalregister.gov/d/2026-22866**, and on **https://govinfo.gov**

4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

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

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: Final amendment; order; notification of partial denial of petition.

SUMMARY: The Food and Drug Administration (FDA or we) is partially granting a color additive petition submitted by the International Association of Color Manufacturers (IACM or petitioner), by amending our color additive regulations, on the basis of abandonment, to remove the authorized uses of methylene chloride, trichloroethylene, and ethylene dichloride from the list of authorized extraction solvents for annatto extract, paprika oleoresin, and turmeric oleoresin. The petitioner provided data demonstrating that these uses have been permanently abandoned. FDA is denying as moot the portion of the petition proposing that the color additive regulations be amended, on the basis of abandonment, to no longer authorize the use of methylene chloride as a diluent in color additive mixtures in inks for marking fruit and vegetables. This request is moot because the authorization for this use has been removed, on the basis of the Delaney Clause, in response to a separate petition.

DATES: This order is effective [**INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER***]. If any provisions are delayed or stayed by the filing of proper objections, FDA will publish such notification in the *Federal Register*. Submit either electronic or written objections and requests for a hearing on the order by

[**INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER***]. See section IX for further information on the filing of objections.

ADDRESSES: You may submit objections and requests for a hearing as follows. Please note that late, untimely filed objections will not be considered. The https://www.regulations.gov electronic filing system will accept objections until 11:59 p.m. Eastern Time at the end of [**INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER***]. Objections 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 objections in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Objections submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your objection will be made public, you are solely responsible for ensuring that your objection 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 objection, that information will be posted on https://www.regulations.gov.
- If you want to submit an objection with confidential information that you do not wish to be made available to the public, submit the objection 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 objections submitted to the Dockets Management Staff, FDA will post your objection, 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 "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 objections, 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 an objection with confidential information that you do not wish to be made publicly available, submit your objection 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 objections. 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 objections 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 Regulations and International Programs, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2378.

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I. Introduction

In the *Federal Register* of April 1, 2026 (91 FR 16169), we announced that we filed a color additive petition (CAP 5C0340) submitted by IACM, 1101 17th St. NW, Suite 700, Washington, DC 20036.

The petition proposed 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 proposed 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 fruit and vegetables. The petition identified §§ 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). The petition requested that we make these amendments on the basis that these uses of the solvents have been permanently abandoned.

The substances that were 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 notification of petition gave interested parties until June 1, 2026, to submit comments on the filed color additive petition, which was made available in the docket.

II. Background

The Federal Food, Drug, and Cosmetic Act (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" 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 ("color" includes black, white, and intermediate grays) thereto (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 (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. 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). 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).

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.

III. Evaluation of Abandonment

A. 21 CFR 73.30 "Annatto extract," 21 CFR 73.345 "Paprika oleoresin," and 21 CFR 73.615 "Turmeric oleoresin"

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 recipients of the survey to verify that they do not:

- Currently manufacture, purchase, use, or import annatto extract (§ 73.30), paprika oleoresin (§ 73.345), and/or turmeric oleoresin (§ 73.615) 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 United States 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).

In addition, when we published the notification of filing of CAP 5C0340, stakeholders had an opportunity to provide information regarding whether any of the three solvents were still being used in the manufacture of the subject color additives. We received no comments that demonstrated current use, which is further evidence supporting the petitioner's claim that these uses are abandoned.

In light of the evidence submitted in the petition, as well as the absence of any evidence demonstrating lack of abandonment, we are granting the petition's requests with respect to §§ 73.30, 73.345, and 73.615. We conclude that methylene chloride, trichloroethylene, and ethylene dichloride have been abandoned with respect to their use in the manufacture of color

additives. Accordingly, FDA is removing the authorizations for the use of these substances in §§ 73.30, 73.345, and 73.615.

B. 21 CFR 73.1 "Diluents in color additive mixtures for food use exempt from certification"

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.

Related to CAP 5C0340, elsewhere in this issue of the *Federal Register*, we published a final order in response to CAP 4C0327 granting that petition, in part, and amending § 73.1 to no longer provide for the use of methylene chloride as a diluent in color additive mixtures for use in inks for marking fruit and vegetables on the basis of the Delaney Clause (section 721(b)(5)(B) of

the FD&C Act). Because the final order issued in response to CAP 4C0327 removes methylene chloride from § 73.1, the petitioner's request based on abandonment is moot.

IV. Comments Related to the Petition

We provided 60 days for comments on the petition. We received one comment, which supported the petitioner's conclusion that the uses of methylene chloride, trichloroethylene, and ethylene dichloride as described in the petition have been abandoned. We received no other comments in response to the notification of petition.

V. Conclusion

FDA reviewed the data and other information in the petition and other available relevant material to evaluate whether the uses of these extraction solvents in the manufacture of color additives have been abandoned. Based on the available information, we have determined that these uses have been abandoned. Therefore, we are amending §§ 73.30, 73.345, and 73.615 of the color additive regulations to no longer provide for the uses of methylene chloride, trichloroethylene, or ethylene dichloride in the manufacture of color additives because these uses have been abandoned. Although the regulatory text in §§ 73.1030 and 73.2030 will not be amended, these regulations are also affected because they authorize the use of these substances by cross-referencing § 73.30. Therefore, in removing the authorization of the use of these substances from § 73.30, their use is no longer authorized under §§ 73.1030 and 73.2030.

We are denying as moot the request to remove methylene chloride from § 73.1 because elsewhere in this issue of the *Federal Register*, FDA has revoked the authorization for methylene chloride as a diluent in color additive mixtures in inks for marking fruit and vegetables on the basis of the Delaney Clause.

VI. Public Disclosure

In accordance with § 71.15 (21 CFR 71.15), the petition and the documents that we considered and relied upon in reaching our decision to approve the petition will be made available for public disclosure (see FOR FURTHER INFORMATION CONTACT). As provided

in § 71.15, we will delete from the documents any materials that are not available for public disclosure. As stated in the notification of filing for CAP 5C0340, the petition is available in the docket.

VII. Analysis of Environmental Impacts

As stated in the April 1, 2026, *Federal Register* notification of petition for CAP 5C0340 (91 FR 16169), the petitioner claimed that this action is categorically excluded under § 25.32(m) (21 CFR 25.32(m)), which applies to "action(s) to prohibit or otherwise restrict or reduce the use of a substance in food, food packaging, or cosmetics." We further stated that, if FDA determines a categorical exclusion applies, neither an environmental assessment nor an environmental impact statement is required. We did not receive any new information or comments regarding this claim of categorical exclusion. We considered the petitioner's claim of categorical exclusion and determined that this action is categorically excluded under § 25.32(m) (Ref. 1). Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Paperwork Reduction Act of 1995

This order contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

IX. Objections

This order is effective as shown in the "DATES" section, except as to any provisions that may be stayed by the filing of proper objections. If you will be adversely affected by one or more provisions of this regulation, you may file with the Dockets Management Staff (see ADDRESSES) either electronic or written objections. You must separately number each objection, and within each numbered objection you must specify with particularity the provision(s) to which you object, and the grounds for your objection. Within each numbered objection, you must specifically state whether you are requesting a hearing on the particular provision that you specify in that numbered objection. If you do not request a hearing for any particular objection, you waive the right to a hearing on that objection. If you request a hearing,

your objection must include a detailed description and analysis of the specific factual information you intend to present in support of the objection in the event that a hearing is held. If you do not include such a description and analysis for any particular objection, you waive the right to a hearing on the objection.

Any objections received in response to the regulation may be seen in the Dockets Management Staff office between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at https://www.regulations.gov. We will publish notice of the objections that we have received or lack thereof in the *Federal Register*.

X. References

The following references 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 are also available electronically at https://www.regulations.gov.

1. Memorandum from A. Thompson-Wood, Environmental Review Team, Office of Pre-Market Additive Safety, Office of Food Chemical Safety, Dietary Supplements and Innovation, Human Foods Program, FDA to D. Hlavaty, Division of Additives and Ingredients, Office of Post-Market Assessment, Office of Food Chemical Safety, Dietary Supplements and Innovation, Human Foods Program, FDA, October 21, 2026.

List of subjects in 21 CFR Part 73

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

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 73 is amended as follows:

PART 73--LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

1. The authority citation for part 73 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e.

§ 73.30 [Amended]

2. Amend § 73.30(a)(1)(ii) by removing “ethylene dichloride”, “methylene chloride”, and “trichloroethylene”.

§ 73.345 [Amended]

3. Amend the list in § 73.345(a)(1) by removing “Ethylene dichloride”, “Methylene chloride”, and “Trichloroethylene”.

§ 73.615 [Amended]

4. Amend the list in § 73.615(a)(1) by removing “Ethylene dichloride”, “Methylene chloride”, and “Trichloroethylene”.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026-22866 Filed: 11/9/2026 8:45 am; Publication Date: 11/10/2026]