

Overall Burden of the Testing and Component Part Regulations on Small Businesses

- To what extent, if any, have children's product manufacturers increased their use of third party testing in response to the third party testing requirements in section 14 of the CPSA and 16 CFR parts 1107 and 1109? Did third party testing replace other types of testing or quality assurance activities that the manufacturers or importers had been using to ensure that their products complied with the applicable product safety rules?

- Is it possible to estimate the overall burden of the testing and component part regulations, perhaps as a percentage of revenue, over and above what businesses would have spent to ensure compliance with the applicable product safety rules in the absence of the testing and component part regulation?

Alberta E. Mills,

Secretary, Consumer Product Safety Commission.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. FDA-2019-C-1782]

CooperVision, Inc.; Withdrawal of Color Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; withdrawal of petition.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the withdrawal, without prejudice to a future filing, of a color additive petition (CAP 9C0315) proposing that the color additive regulations be amended to provide for the safe use of disperse orange 3 methacrylamide as a color additive in contact lenses.

DATES: The color additive petition was withdrawn on June 15, 2020.

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 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.

FOR FURTHER INFORMATION CONTACT:

Molly A. Harry, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1075.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 8, 2019 (84 FR 20060), we announced that we had filed a color additive petition (CAP 9C0315), submitted by CooperVision, 5870 Stoneridge Dr., Suite 1, Pleasanton, CA 94588. The petition proposed to amend the color additive regulations in 21 CFR part 73, *Listing of Color Additives Exempt from Certification*, to provide for the safe use of disperse orange 3 methacrylamide (CAS Reg. 58142-15-7; CAS name 2-propenamide, 2-methyl-N-[4-[2-(4-nitrophenyl)diazenyl]phenyl]-) as a color additive in silicone-based hydrogel contact lenses. The color additive was intended to copolymerize with various monomers in the contact lens formulation to produce colored contact lenses. Through this notice, we are announcing that CooperVision has withdrawn the petition without prejudice to a future filing (21 CFR 71.6(c)(2)).

Dated: July 31, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Part 7

[FAR Case 2019-001, Docket No. FAR-2019-0020, Sequence No. 1]

RIN 9000-AN84

Federal Acquisition Regulation: Analysis for Equipment Acquisitions

AGENCY: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Proposed rule.

SUMMARY: DoD, GSA, and NASA are proposing to amend the Federal Acquisition Regulation (FAR) to implement a section of the FAA Reauthorization Act of 2018, which requires, when acquiring equipment, a case-by-case analysis of cost and other factors associated with certain methods of acquisition, including purchase,

short-term rental or lease, long-term rental or lease, interagency acquisition, and, if applicable, acquisition agreements with a State or local government.

DATES: Interested parties should submit written comments at the address shown below on or before October 23, 2020 to be considered in the formation of the final rule.

ADDRESSES: Submit comments in response to FAR Case 2019-001 to [Regulations.gov](https://www.regulations.gov): <http://www.regulations.gov>. Submit comments via the Federal eRulemaking portal by searching for "FAR Case 2019-001". Select the link "Comment Now" that corresponds with FAR Case 2019-001. Follow the instructions provided at the "Comment Now" screen. Please include your name, company name (if any), and "FAR Case 2019-001" on your attached document. If your comment cannot be submitted using <https://www.regulations.gov>, call or email the points of contact in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

Instructions: Please submit comments only and cite "FAR case 2019-001" in all correspondence related to this case. All comments received will be posted without change to <http://www.regulations.gov>, including any personal and/or business confidential information provided.

FOR FURTHER INFORMATION CONTACT: Mr. Michael O. Jackson, Procurement Analyst, at 202-208-4949, or by email at michaelo.jackson@gsa.gov, for clarification of content. For information pertaining to status or publication schedules, contact the Regulatory Secretariat Division at 202-501-4755 or GSARegSec@gsa.gov. Please cite FAR case 2019-001.

SUPPLEMENTARY INFORMATION:

I. Background

On July 16, 2013, DoD, GSA, and NASA published a Request for Information (RFI) in the **Federal Register** (78 FR 42524) to determine whether there is a distinction between renting and leasing that is useful for the purposes of FAR subpart 7.4. The public comment period closed in September 2013 and 13 respondents provided comments in response to the RFI. A review of the public comments identified that there are differences between renting and leasing in many industries, but there are no standard differences between renting and leasing that span across all industries. As a result of the review, FAR case 2017-017 was opened to clarify the term "lease", as used in the FAR and a proposed rule

was published in the **Federal Register** on September 5, 2018, at 83 FR 45072; six respondents provided comments in response to the proposed rule.

On October 5, 2018, the FAA Reauthorization Act of 2018 (Pub. L. 115–254) became law and included section 555, “Cost-Effectiveness Analysis of Equipment Rental.” (FAA stands for Federal Aviation Administration.) FAR case 2017–017 was subsequently closed and this FAR case 2019–001 was opened to implement the requirements of section 555. The Civilian Agency Acquisition Council and the Defense Acquisition Regulations Council (the Councils) reviewed the public comments received in response to FAR case 2017–017 in developing this proposed rule and are dispositioned in this notice.

This rule implements section 555 of the FAA Reauthorization Act of 2018, which:

- Requires an agency to acquire equipment using the method of acquisition that is most advantageous to the Government based on a case-by-case analysis of comparative costs and other factors (to include the factors in FAR section 7.401);
- Identifies methods of acquisition that must be considered, at a minimum, in the analysis; and
- Requires the FAR to implement the requirements of the section and identify the factors agencies should or shall consider to perform the case-by-case analysis.

II. Discussion and Analysis

To implement the requirements of the law, described above, this rule proposes to amend FAR subpart 7.4 to: Require the comparison of purchase, short-term rental or lease, long-term rental or lease, interagency acquisition, and agency acquisition agreements with State or local governments as a method of acquisition for equipment; include the term “rent,” where applicable; and add factors to be considered when evaluating various methods of acquisition.

A discussion of the comments received under proposed rule 2017–017 is provided as follows:

1. Support for the Rule

Comment: Several of the respondents expressed support for the rule.

Response: The Councils acknowledge the public support for the rule.

2. Incorporate Section 555 Into the Proposed Rule

Comment: A respondent advised that the proposed rule should be modified to

incorporate section 555 of the FAA Reauthorization Act of 2018.

Response: FAR case 2017–017 was closed and rolled into FAR case 2019–001, specifically to implement section 555 of the FAA Reauthorization Act of 2018.

3. Factors To Consider

Comment: A number of respondents suggested the following additional factors that could be considered in the analysis and decision to rent, lease, or purchase equipment—

- How long the equipment is needed and how long it will be in use (or its useful life);
- Cancellation, extension, and early return conditions in the agreement;
- Maintenance requirements for the equipment and the cost to the Government under various acquisition methods, to include any maintenance requirements specific to an industry (e.g., test and measurement equipment);
- Whether the agreement includes an option to purchase the equipment, and, if so, the cost benefit to the Government in such an option;
- Repair, transport, storage, insurance, environmental and licensing requirements for the equipment and the cost to the Government under various acquisition methods;
- Whether the equipment can be swapped out or exchanged;
- Availability or delivery of equipment to meet Government needs and timeline.

Response: While section 555 serves as the main impetus for this proposed rule, the suggestions and comments on FAR case 2017–017 have been taken into account and additional factors have been added to FAR 7.401(b)(1) and (b)(2).

4. Renting/Leasing

Comment: Several respondents expressed concern that the proposed rule did not clarify the differences between renting and leasing, including those specific to the heavy equipment industry, and that without this recognition, the Government will waste money by grouping these two categories together.

Response: Additional considerations unique to renting have been added to FAR 7.401(b)(1) and (b)(2). However, the proposed rule does not differentiate between rent and leasing because there are no standard differences between these practices that span across all industries. As a result, the recommended clarification could have the unintended consequence of creating new confusion.

Comment: Several respondents recommended implementing a separate

“rental method” of acquisition, in order to identify the unique properties and benefits of renting. A respondent asserts that codification of a definitive definition of “rental method”, “equipment rental”, and “lease method” is necessary for contracting officers to understand the differences between both methods, and impossible for the Government to execute a rental agreement.

Response: The purpose of FAR subpart 7.4 is to facilitate an analysis and a decision on whether it is in the best interest of the Government to purchase a piece of equipment versus obtaining the equipment via any other non-purchase method. As a result, this case includes the word “rent” throughout FAR subpart 7.4 text, to ensure that contracting officers are aware that rental agreements are an acceptable non-purchase acquisition method for equipment, and implements additional factors to be considered in the analysis that account for the unique benefits that rental agreements may provide for the Government.

Comment: A respondent advised that defining the difference between renting and leasing will help agencies meet their small business goals, as a majority of heavy equipment leases would fall under the simplified acquisition threshold and; therefore, be awarded to small businesses.

Response: This rule proposes to add the word “rent” throughout the text of FAR subpart 7.4, as appropriate, to ensure contracting officers are aware that rental agreements are an acceptable non-purchase method of equipment acquisition.

5. Guidance/Resources

Comment: A respondent advised that providing acquisition officials with the guidance in OMB Circular A–94 will cause confusion, as the guidance does not apply to short-term rentals and eliminates the possibility that an acquisition official would consider rental as an acquisition option since the proposed rule makes rentals and leases synonymous.

Response: The purpose of referring to the OMB Circular is to make the contracting officer aware of additional information that may be relevant in determining the method of acquisition that is most advantageous to the Government. The reference is not intended to preclude consideration of rent as a method of acquisition, but respondents to the proposed rule are encouraged to offer suggested clarifications.

Comment: A respondent suggested that the GSA website provided to

contracting officers for additional information may be too narrow of a resource, as it pertains to a program that is akin to a hardware store, home improvement center, or are maintenance, repair, and operations supplies. The respondent recommends providing another resource that can assist agencies with rental, lease, or purchase decisions for a broader scope of products.

Response: The GSA customer service information and website at FAR 7.403(b)(1) and (b)(2) are provided as current sources Federal agencies may use when they need assistance with a buy, rent, or lease decision. Agencies may provide supplemental guidance, as needed, to meet their unique needs and requirements.

6. Amend GSA Security Schedule

Comment: A respondent recommended amending the GSA Security Schedule 84 to permit leasing of equipment, by Federal, State, and Local law enforcement and emergency response agencies, through the schedule contracts and make conforming changes within the contract that clarify the applicable terms and conditions that apply when purchasing versus leasing equipment under the Schedule.

Response: This comment is outside the scope of FAR case 2017–017 and the scope of the current proposed rule.

III. Applicability to Contracts at or Below the Simplified Acquisition Threshold (SAT) and for Commercial Items, Including Commercially Available Off-the-Shelf (COTS) Items

This proposed rule does not create any new provisions or clauses, nor does it change the applicability of any existing provisions or clauses included in solicitations and contracts valued at or below the SAT, or for commercial items, including COTS items.

IV. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This

proposed rule is not a major rule under 5 U.S.C. 804.

V. Executive Order 13771

The rulemaking is not subject to E.O. 13771, because this proposed rule is not a significant regulatory action under E.O. 12866.

VI. Regulatory Flexibility Act

DoD, GSA, and NASA do not expect this rulemaking to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* However, an initial regulatory flexibility analysis has been performed and is summarized as follows:

The Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA) are proposing to revise the Federal Acquisition Regulation (FAR) to require, when acquiring equipment, a case-by-case analysis of cost and other factors associated with certain methods of acquisition.

The objective of the rule is to ensure agencies acquire equipment using the method of acquisition that is most advantageous to the Government based on a case-by-case analysis of comparative costs and other factors. The legal basis for the rule is section 555 of the FAA Reauthorization Act of 2018 (Pub. L. 115–254).

DoD, GSA, and NASA do not expect this rule to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* The rule primarily affects internal Government requirements determination decisions, acquisition strategy decisions, and contract file documentation requirements. The Government does not collect data on the total number of solicitations issued on an annual basis that are subject to the analysis of FAR subpart 7.4. However, the Federal Procurement Data System (FPDS) collects information on the product service code (PSC) assigned to a contract based on the predominant supply or service being acquired. FPDS data for FY 2016–2018, on PSCs for approximately 100 types of equipment and 80 types of equipment rental or lease services, indicates that the Federal Government awards an average of 125,940 new contracts and orders annually; of which approximately 54,845 (44 percent) were awarded to approximately 6,940 unique small businesses.

The proposed rule does not impose any Paperwork Reduction Act reporting or recordkeeping requirements on any small entities. The proposed rule does not duplicate, overlap, or conflict with any other Federal rules. There are no known significant alternative approaches to the proposed rule that would meet the proposed objectives.

The Regulatory Secretariat has submitted a copy of the IRFA to the Chief Counsel for Advocacy of the Small Business Administration. A copy of the IRFA may be obtained from the

Regulatory Secretariat. DoD, GSA and NASA invite comments from small business concerns and other interested parties on the expected impact of this rulemaking on small entities.

DoD, GSA, and NASA will also consider comments from small entities concerning the existing regulations in subparts affected by this proposed rule consistent with 5 U.S.C. 610. Interested parties must submit such comments separately and should cite 5 U.S.C. 610 (FAR Case 2019–001) in correspondence.

VII. Paperwork Reduction Act

The proposed rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

List of Subjects in 48 CFR Part 7

Government Procurement.

William F. Clark,

Director, Office of Government-Wide Acquisition Policy, Office of Acquisition Policy, Office of Government-Wide Policy.

Therefore, DoD, GSA, and NASA propose amending 48 CFR part 7 as set forth below:

PART 7—ACQUISITION PLANNING

■ 1. The authority citation for 48 CFR part 7 continues to read as follows:

Authority: 40 U.S.C. 121(c); 10 U.S.C. chapter 137; and 51 U.S.C. 20113.

■ 2. Revise the heading of subpart 7.4 to read as follows:

Subpart 7.4—Equipment Acquisition

■ 3. Revise section 7.400 to read as follows:

7.400 Scope of subpart.

This subpart—

(a) Implements section 555 of the FAA (Federal Aviation Administration) Reauthorization Act of 2018 (Pub. L. 115–254);

(b) Provides guidance when acquiring equipment and more than one method of acquisition is available for use; and

(c) Applies to both the initial acquisition of equipment and the renewal or extension of existing equipment leases or rental agreements.

■ 4. Revise section 7.401 to read as follows:

7.401 Acquisition considerations.

(a)(1) Agencies shall acquire equipment using the method of acquisition most advantageous to the Government based on a case-by-case

analysis of comparative costs and other factors in accordance with this subpart and agency procedures.

(2) The methods of acquisition to be compared in the analysis shall include, at a minimum—

- (i) Purchase;
- (ii) Short-term rental or lease;
- (iii) Long-term rental or lease;
- (iv) Interagency acquisition (see 2.101); and
- (v) Agency acquisition agreements, if applicable, with a State or local government.

(b)(1) The factors to be compared in the analysis shall include, at a minimum:

- (i) Estimated length of the period the equipment is to be used and the extent of use within that period;
- (ii) Financial and operating advantages of alternative types and makes of equipment;
- (iii) Cumulative rent, lease, or other periodic payments, however described, for the estimated period of use;
- (iv) Net purchase price;
- (v) Transportation, installation, and storage costs;
- (vi) Maintenance, repair, and other service costs; and
- (vii) Potential obsolescence of the equipment because of imminent technological improvements.

(2) The following additional factors should be considered, as appropriate, depending on the type, cost, complexity, and estimated period of use of the equipment:

- (i) Availability of purchase options.
- (ii) Cancellation, extension, and early return conditions and fees.
- (iii) Ability to swap out or exchange equipment.
- (iv) Available warranties.
- (v) Insurance, environmental, or licensing requirements.
- (vi) Potential for use of the equipment by other agencies after its use by the acquiring agency is ended.
- (vii) Trade-in or salvage value.
- (viii) Imputed interest.
- (ix) Availability of a servicing capability, especially for highly

complex equipment; e.g., can the equipment be serviced by the Government or other sources if it is purchased?

(c) The analysis in paragraph (a) is not required—

(1) When the President has issued an emergency declaration or a major disaster declaration pursuant to the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121 *et seq.*);

(2) In other emergency situations if the agency head makes a determination that obtaining such equipment is necessary in order to protect human life or property; or

(3) When otherwise authorized by law.

■ 5. Amend section 7.402 by—

- a. Removing from paragraph (a)(1) “cumulative leasing” and adding “cumulative rental or leasing” in its place;
- b. Removing from paragraph (a)(2) “favor of leasing” and adding “favor of renting or leasing” in its place;
- c. Revising the heading and introductory text of paragraph (b)(1);
- d. Revising paragraph (b)(2);
- e. Removing from paragraph (b)(3) “long term lease” and adding “long term rental or lease agreement” in its place; and
- f. Removing from paragraph (b)(4) “If a lease with option” and adding “If a rental or lease agreement with option” in its place.

The revised text reads as follows:

7.402 Acquisition methods.

* * * * *

(b) *Rent or lease method.* (1) The rent or lease method is appropriate if it is to the Government’s advantage under the circumstances. The rent or lease method may also serve as a short-term measure when the circumstances—

* * * * *

(2) If a rent or lease method is justified, a rental or lease agreement with option to purchase is preferable.

* * * * *

■ 6. Amend section 7.403 by—

- a. Revising the section heading;
- b. Removing from paragraph (a) “in lease or” and adding “in lease, rent, or” in its place;
- c. Revising paragraph (b); and
- d. Adding paragraph (c).

The revised and added text reads as follows:

7.403 General Services Administration assistance and OMB Guidance.

* * * * *

(b) For additional GSA assistance and guidance, agencies may—

(1) Request information from the GSA FAS National Customer Service Center by phone at 1-800-488-3111 or by email at ncscustomer.service@gsa.gov; and

(2) See GSA website, Schedule 51 V Hardware Superstore—Equipment Rental, (<https://www.gsa.gov/acquisition/purchasing-programs/gsa-schedules/list-of-gsa-schedules/schedule-51-vhardware-superstore/equipment-rental-and-leasing>).

(c) For additional OMB guidance, see—

(1) Section 13, Special Guidance for Lease-Purchase Analysis, and paragraph 8.c.(2), Lease-Purchase Analysis, of OMB Circular A-94, Guidelines and Discount Rates for Benefit-Cost Analysis of Federal Programs, (<https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A94/a094.pdf>); and

(2) Appendix B, Budgetary Treatment of Lease-Purchases and Leases of Capital Assets, of OMB Circular A-11, Preparation, Submission, and Execution of the Budget, (https://www.whitehouse.gov/wp-content/uploads/2018/06/app_b.pdf).

7.404 [Amended]

■ 7. Removing from the text “a lease with” and adding “a rental or lease agreement with” in its place.

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