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LATHAM&WATKINS LLP

November 17, 2020

FILED VIA ECF

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National Organization of Veterans' Advocates, Inc., et al. v. Secretary of Re: Veterans Affairs, No. 20-1321

Dear Mr. Marksteiner:

Pursuant to Federal Rule of Appellate Procedure 28(i), Petitioners advise the Court of a final rule recently promulgated by the Department of Veterans Affairs (VA), Administrative Procedures: Guidance Documents, 85 Fed. Reg. 72,569 (Nov. 13, 2020) (Exhibit A). This final rule implements Executive Order (EO) 13891, Promoting the Rule of Law Through Improved Agency Guidance Documents, 84 Fed. Reg. 55,235 (Oct. 9, 2019) (Exhibit B). VA's final rule sheds important light on the ordinary and administrative-law meaning of the phrase "interpretations of general applicability" in 5 U.S.C. § 552(a)(1)(D) (emphasis added).

EO 13891 directs agencies to issue regulations governing the issuance and legal import of "non-binding guidance documents," defined to include certain "agency statement[s] of general applicability." 84 Fed. Reg. at 55,235 (emphasis added). VA's final rule "clarifies"—and elaborates upon-that definition by making clear that an agency statement "of general applicability" is simply one that "applies to more than just one person, event, or transaction":

> Guidance document means an agency statement of general applicability (i.e., it applies to more than just one person, event, or transaction), that is intended to have a future effect on the behavior or actions of regulated parties (to include non-VA actors), and that sets forth a policy on a statutory, regulatory, or technical issue, or an interpretation of a statute or regulation.

85 Fed. Reg. at 72,569, 72,570-71 (codified at 38 C.F.R. § 5.10) (emphasis added). The final rule also recognizes, consistent with EO 13891, that such guidance documents "of general applicability" are not "bind[ing]." *Id.* at 72,569.

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VA's final rule supports Petitioners' arguments in this case. First, it confirms that the ordinary and well-understood administrative-law meaning of the phrase "of general applicability" is simply "appli[cable] to more than just one person, event, or transaction." *See* NOVA Br. 18-32 (ECF No. 53). Second, it confirms that an agency statement can be "of general applicability" even if it is not "binding." *See id.* at 38-44. VA's final rule thus undermines VA's argument that Section 552(a)(1)(D)'s phrase "of general applicability" does *not* encompass interpretations unless they *are* binding. *See* VA Br. 21-30 (ECF No. 78).

Respectfully submitted,

/s/ Roman Martinez
Roman Martinez
Counsel for Petitioners

cc: Counsel of Record (via ECF)

EXHIBIT A

your search to documents published by the Department.

Reed D. Rubinstein,

Principal Deputy General Counsel delegated the authority to perform the functions and duties of the General Counsel for the Office of the General Counsel.

[FR Doc. 2020–23526 Filed 11–12–20; 8:45 am]

BILLING CODE 4000-01-P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 5

RIN 2900-AQ92

Administrative Procedures: Guidance Documents

AGENCY: Department of Veterans Affairs. **ACTION:** Final rule.

SUMMARY: The Department of Veterans Affairs (VA) is establishing in regulation its processes and procedures for issuing guidance documents. This final rulemaking will implement the mandates of Executive Order 13891, Promoting the Rule of Law Through Improved Agency Guidance Documents. DATES: This rule is effective December 14, 2020.

FOR FURTHER INFORMATION CONTACT:

Richard Murphy, Office of Policy and Interagency Collaboration, Office of Enterprise Integration, 810 Vermont Avenue NW, Washington, DC 20420, (202) 714–8507. (This is not a toll-free telephone number).

SUPPLEMENTARY INFORMATION: On October 9, 2019, the President signed Executive Order (E.O.) 13891, Promoting the Rule of Law Through Improved Agency Guidance Documents.

Section 4 of the E.O. mandates that each agency finalize regulations to set forth processes and procedures for issuing guidance documents. This rule complies with that mandate by adding part 5 to title 38 Code of Federal Regulations (38 CFR part 5). Part 5 is titled "Administrative Procedures: Guidance Documents," and informs the public about VA's general processes and procedures for issuing guidance documents. Prior to this rulemaking, VA has not previously published procedures relating to the issuance of guidance documents.

5.0 Purpose

VA is stating the purpose of part 5 in § 5.0, which is to provide VA's processes and procedures for issuing and managing guidance documents in accordance with E.O. 13891. Section 4 of the E.O. requires each agency to

finalize regulations or amend existing regulations to set forth processes and procedures for issuing guidance documents within 300 days of the date on which the Office of Management and Budget (OMB) issues an implementing memorandum under section 6 of the E.O.. OMB issued its memorandum, M-20-02, on October 31, 2019. Section 4 of the E.O.; shall require that each guidance document clearly state that it does not bind the public, except as authorized by law or as incorporated into a contract; and shall include procedures for the public to petition for withdrawal or modification of a particular guidance document. For significant guidance documents, section 4 of the E.O. contains additional requirements. These include that there must be a period of notice and comment of at least 30 days and a public response from the agency to major concerns raised in comments, except when the agency for good cause finds that notice and comment are impracticable, unnecessary, or contrary to public interest. Significant guidance documents must be approved on a nondelegable basis by the agency head or agency component head appointed by the President. They must be reviewed by OIRA under E.O. 12866 before issuance, and they must comply with applicable requirements for significant regulatory actions set forth in E.O.s. 12866, 13563, 13609, 13771, and 13777.

5.10 Definitions Relating to Guidance Documents

Section 5.10 is the definitions section. The section generally tracks the requirements of E.O. 13891, as applied to VA. Because the definition of guidance document is broad, this rule clarifies that a guidance document is an agency statement of general applicability (i.e., it applies to more than just one person, event, or transaction), that is intended to have a future effect on the behavior or actions of regulated parties (to include non-VA actors), and that sets forth a policy on a statutory, regulatory, or technical issue, or an interpretation of a statute or regulation. The section mirrors the exclusion in section 2(b)(i)-(vi) of the E.O. for those documents that VA does not consider guidance documents.

VA is mirroring the definition of significant guidance document to that provided in section 2(c) of the E.O. with minor clarifying edits.

VA is also defining VA to mean the Department of Veterans Affairs.

5.15 Procedures for Issuing Guidance Documents

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VA is implementing the requirements of section 4(a)(i) and (iii) of the E.O. in § 5.15. We are stating the requirements of section 4(a)(i) in paragraph (a)(1) by stating that each guidance document must clearly and prominently state that it does not bind the public, except as authorized by law or as incorporated into a contract. VA is adding sample language of the disclaimer for guidance documents as follows: The contents of this document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to the public regarding existing requirements under the law or agency policies.

Paragraph 5.15(a)(2) states the information that must be included in each guidance document. VA is stating that a guidance document must include the following information: The term guidance; the agency or office issuing the document; to what and to whom the document applies; the date of issuance; title and unique identification number of the document; citation to statutory or regulatory authority that the guidance document interprets or applies; a short summary of the subject matter covered at the beginning of the guidance document; the statement required under paragraph (a)(1) of this section; and as applicable, the guidance document being revised or replaced.

Paragraph 5.15(b) states the procedures for significant guidance documents as required in section 4(a)(iii) of the E.O. Significant guidance documents must follow the requirements provided in paragraph 5.15(a). Further, unless the Administrator of the Office of Management and Budget's Office of Information and Regulatory Affairs (OIRA), pursuant to review under E.O. 12866, and VA agree that exigency, safety, health, or other compelling cause warrants an exemption, the following additional procedures apply to significant guidance documents. Paragraph (b)(1) states that VA will provide for a period of public notice and comment of at least 30 days before issuance of such significant guidance document and will provide a public response to major concerns raised in comments, except when VA for good cause finds (and incorporates such finding and a brief statement of reasons therefor into the guidance document) that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest. Paragraph (b)(2) states that the Secretary or a VA component head appointed by

the President must approve any significant guidance document prior to issuance; in addition, pursuant to section 4(a)(iii)(B) of the E.O., this approval authority is not delegable. Paragraph (b)(3) establishes that significant guidance documents must be reviewed by OIRA under E.O. 12866 prior to issuance. Paragraph (b)(4) requires that significant guidance documents comply with the applicable requirements for regulations or rules set forth in E.O.s 12866, 13563, 13609, 13771, and 13777.

5.20 Procedures for Petition for the Withdrawal or Modification of a Guidance Document

Section 5.20 implements the requirements in section 4(a)(ii) of the E.O and states the procedures for the public to petition for the withdrawal or modification of a guidance document. Paragraph (a) provides the addresses for submitting such petitions. The email address is: OEIDMO@va.gov. The public may also submit requests via mail to the following address: Office of Policy and Interagency Collaboration, Office of Enterprise Integration, 810 Vermont Avenue NW, Washington, DC 20420.

Paragraph (b) provides the information that must be included in a petition, including: (1) The petitioner's name and address; (2) information identifying the guidance document to which the petition pertains; and (3) a statement of the reasons the petitioner believes the document should be withdrawn or modified.

We are stating in paragraph (c) that VA will provide a response to such petition within 90 days of receipt of the request.

5.25 Guidance Website

Section 5.25 states that VA has a guidance website that contains, or links to, guidance documents that are currently in effect and that VA will not cite, use, or rely on any guidance document that is not posted on the website existing under E.O. 13891, except to establish historical facts. Section 5.25 further provides the address for the guidance portal that is required by section 3 of E.O. 13891. The guidance portal can be accessed at www.VA.gov/guidance.

Administrative Procedure Act

The Secretary of Veterans Affairs is publishing this rule without prior opportunity for public comment pursuant to 5 U.S.C. 553(b)(A) as this rule is a rule of agency organization, procedure, or practice, and thus is published as a final rule.

Paperwork Reduction Act

This rule contains no provisions constituting a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521).

Regulatory Flexibility Act

The Secretary hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. The regulations established by this rulemaking do not impose burdens or otherwise regulate the activities of any entities outside of VA. Therefore, pursuant to 5 U.S.C. 605(b), the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604 do not apply.

Executive Orders 12866, 13563 and 13771

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). E.O. 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. OIRA has determined that this rule is not a significant regulatory action under E.O. 12866. VA's impact analysis can be found as a supporting document at http:// www.regulations.gov, usually within 48

hours after the rulemaking document is published. Additionally, a copy of the rulemaking and its impact analysis are available on VA's website at http://www.va.gov/orpm/, by following the link for "VA Regulations Published From FY 2004 Through Fiscal Year to Date."

This final rule is not expected to be an E.O. 13771 regulatory action because this final rule is not significant under E.O. 12866.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more (adjusted annually for inflation) in any one year. This final rule would have no

such effect on State, local, and tribal governments, or on the private sector.

Catalog of Federal Domestic Assistance

There are no Catalog of Federal Domestic Assistance numbers and titles for this rule.

Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), OIRA designated this rule as not a major rule, as defined by 5 U.S.C. 804(2).

List of Subjects in 38 CFR Part 5

Administrative practice and procedure.

Signing Authority

The Secretary of Veterans Affairs approved this document on November 6, 2021, for publication and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs.

Jeffrey M. Martin,

Assistant Director, Office of Regulation Policy & Management, Office of the Secretary, Department of Veterans Affairs.

■ For the reasons stated in the preamble, the Department of Veterans Affairs adds 38 CFR part 5 as follows:

PART 5—Administrative Procedures: Guidance Documents

Sec.

5.0 Purpose.

5.10. Definitions relating to guidance documents.

5.15. Procedures for issuing guidance documents.

5.20. Procedures for petition for the withdrawal or modification of a guidance document

5.25. Guidance website.

Authority: 38 U.S.C. 501; E.O. 13891, 84 FR 55235.

§5.0 Purpose.

Sections 5.0 through 5.25 provide VA's processes and procedures for issuing and managing guidance documents in accordance with Executive Order 13891.

§ 5.10 Definitions relating to guidance documents.

The following definitions apply to §§ 5.0 through 5.25.

Guidance document means an agency statement of general applicability (i.e., it applies to more than just one person, event, or transaction), that is intended to have a future effect on the behavior or actions of regulated parties (to include non-VA actors), and that sets forth a policy on a statutory, regulatory, or

technical issue, or an interpretation of a statute or regulation. A guidance document does not include the following:

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- (1) Rules promulgated pursuant to notice and comment under section 553 of title 5, United States Code, or similar statutory provisions;
- (2) Rules exempt from rulemaking requirements under section 553(a) of title 5, United States Code;
- (3) Rules of agency organization, procedure, or practice;
- (4) Decisions of agency adjudications under section 554 of title 5, United States Code, or similar statutory provisions;
- (5) Internal guidance directed to the issuing agency or other agencies that is not intended to have substantial future effect on the behavior of regulated parties; or
- (6) Internal executive branch legal advice or legal opinions addressed to executive branch officials.
- Significant guidance document means a guidance document that the Administrator of the Office of Information and Regulatory Affairs determines is reasonably anticipated to:
- (1) Lead to an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;
- (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
- (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or
- (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles of Executive Order 12866.

VA means the Department of Veterans Affairs.

§ 5.15 Procedures for issuing guidance documents.

(a) General. (1) Each guidance document must clearly and prominently state that it does not bind the public, except as authorized by law or as incorporated into a contract. Guidance documents may include the following or similar disclaimer language: The contents of this document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to the public regarding existing requirements under the law or agency policies.

- (2) Each guidance document must include the following information in the published guidance document:
 - (i) The term guidance;
- (ii) The agency or office issuing the document;
- (iii) To what and to whom the document applies;
 - (iv) The date of issuance;
- (v) The title and unique identification number of the document;
- (vi) Citation to statutory or regulatory authority that the guidance document interprets or applies;
- (vii) A short summary of the subject matter covered at the beginning of the guidance document;
- (viii) The statement required under paragraph (a)(1) of this section; and
- (ix) As applicable, the guidance document being revised or replaced.
- (b) Significant guidance documents. We will refer to the Administrator of the Office of Information and Regulatory Affairs (OIRA) within the Office of Management and Budget, or the Administrator's designee, the question of whether a guidance document is significant. Significant guidance documents must follow the requirements provided in paragraph 5.15(a). Additionally, unless the Administrator of OIRA, pursuant to review under E.O. 12866, and VA agree that exigency, safety, health, or other compelling cause warrants an exemption, the following additional procedures apply:
- (1) VA will provide for a period of public notice and comment of at least 30 days before issuance of such significant guidance document and will provide a public response to major concerns raised in comments, except when VA for good cause finds (and incorporates such finding and a brief statement of reasons therefor into the guidance document) that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest.
- (2) The Secretary or a VA component head appointed by the President (with or without confirmation by the Senate), or by an official who is serving in an acting capacity as either of the foregoing, must approve any significant guidance document prior to issuance; pursuant to section 4(a)(iii)(B) of Executive Order 13891, this approval authority is not delegable.
- (3) Significant guidance documents must be submitted to OIRA for review under Executive Order 12866 prior to issuance.
- (4) Significant guidance documents must comply with the applicable requirements for regulations or rules set

forth in Executive Orders 12866, 13563, 13609, 13771, and 13777.

§ 5.20 Procedures for petition for the withdrawal or modification of a guidance document.

Petitions for withdrawal or modification of a guidance document. The following procedures apply for the public to petition for withdrawal or modification of a guidance document.

- (a) A member of the public wishing to petition for withdrawal or modification of a guidance document may submit such petition via email to: *OEIDMO@ va.gov.* Petitions may also be mailed to the following address: Office of Policy and Interagency Collaboration, Office of Enterprise Integration, 810 Vermont Avenue NW, Washington, DC 20420.
- (b) A petition for withdrawal or modification of a guidance document must contain the following information:
 - (1) The petitioner's name and address;
- (2) Information identifying the guidance document to which the petition pertains;
- (3) A statement of the reasons the petitioner believes the document should be withdrawn or modified.
- (c) VA will provide a response to a petition within 90 days of receipt of the request.

§ 5.25 Guidance website.

VA has a guidance website that contains, or links to, guidance documents that are currently in effect. VA will not cite, use, or rely on any guidance document that is not posted on the website existing under Executive Order 13891, except to establish historical facts. The website can be found at the following address: www.VA.gov/guidance.

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2019-0346; FRL-10012-87]

Mefenoxam; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of mefenoxam in or on the tree nut, crop group 14–12 and almond, hulls. Syngenta Crop Protection requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

EXHIBIT B

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55235

Federal Register

Vol. 84, No. 199

Tuesday, October 15, 2019

Presidential Documents

Title 3—

Executive Order 13891 of October 9, 2019

The President

Promoting the Rule of Law Through Improved Agency Guidance Documents

By the authority vested in me as President by the Constitution and the laws of the United States of America, and in order to ensure that Americans are subject to only those binding rules imposed through duly enacted statutes or through regulations lawfully promulgated under them, and that Americans have fair notice of their obligations, it is hereby ordered as follows:

Section 1. Policy. Departments and agencies (agencies) in the executive branch adopt regulations that impose legally binding requirements on the public even though, in our constitutional democracy, only Congress is vested with the legislative power. The Administrative Procedure Act (APA) generally requires agencies, in exercising that solemn responsibility, to engage in notice-and-comment rulemaking to provide public notice of proposed regulations under section 553 of title 5, United States Code, allow interested parties an opportunity to comment, consider and respond to significant comments, and publish final regulations in the Federal Register.

Agencies may clarify existing obligations through non-binding guidance documents, which the APA exempts from notice-and-comment requirements. Yet agencies have sometimes used this authority inappropriately in attempts to regulate the public without following the rulemaking procedures of the APA. Even when accompanied by a disclaimer that it is non-binding, a guidance document issued by an agency may carry the implicit threat of enforcement action if the regulated public does not comply. Moreover, the public frequently has insufficient notice of guidance documents, which are not always published in the *Federal Register* or distributed to all regulated parties.

Americans deserve an open and fair regulatory process that imposes new obligations on the public only when consistent with applicable law and after an agency follows appropriate procedures. Therefore, it is the policy of the executive branch, to the extent consistent with applicable law, to require that agencies treat guidance documents as non-binding both in law and in practice, except as incorporated into a contract, take public input into account when appropriate in formulating guidance documents, and make guidance documents readily available to the public. Agencies may impose legally binding requirements on the public only through regulations and on parties on a case-by-case basis through adjudications, and only after appropriate process, except as authorized by law or as incorporated into a contract.

Sec. 2. *Definitions*. For the purposes of this order:

- (a) "Agency" has the meaning given in section 3(b) of Executive Order 12866 (Regulatory Planning and Review), as amended.
- (b) "Guidance document" means an agency statement of general applicability, intended to have future effect on the behavior of regulated parties, that sets forth a policy on a statutory, regulatory, or technical issue, or an interpretation of a statute or regulation, but does not include the following:
 - (i) rules promulgated pursuant to notice and comment under section 553 of title 5, United States Code, or similar statutory provisions;
 - (ii) rules exempt from rulemaking requirements under section 553(a) of title 5, United States Code;

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(iii) rules of agency organization, procedure, or practice;

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(iv) decisions of agency adjudications under section 554 of title 5, United States Code, or similar statutory provisions;

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- (v) internal guidance directed to the issuing agency or other agencies that is not intended to have substantial future effect on the behavior of regulated parties; or
- (vi) internal executive branch legal advice or legal opinions addressed to executive branch officials.
- (c) "Significant guidance document" means a guidance document that may reasonably be anticipated to:
 - (i) lead to an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;
 - (ii) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
 - (iii) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or
 - (iv) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles of Executive Order 12866.
- (d) "Pre-enforcement ruling" means a formal written communication by an agency in response to an inquiry from a person concerning compliance with legal requirements that interprets the law or applies the law to a specific set of facts supplied by the person. The term includes informal guidance under section 213 of the Small Business Regulatory Enforcement Fairness Act of 1996, Public Law 104–121 (Title II), as amended, letter rulings, advisory opinions, and no-action letters.
- Sec. 3. Ensuring Transparent Use of Guidance Documents. (a) Within 120 days of the date on which the Office of Management and Budget (OMB) issues an implementing memorandum under section 6 of this order, each agency or agency component, as appropriate, shall establish or maintain on its website a single, searchable, indexed database that contains or links to all guidance documents in effect from such agency or component. The website shall note that guidance documents lack the force and effect of law, except as authorized by law or as incorporated into a contract.
- (b) Within 120 days of the date on which OMB issues an implementing memorandum under section 6 of this order, each agency shall review its guidance documents and, consistent with applicable law, rescind those guidance documents that it determines should no longer be in effect. No agency shall retain in effect any guidance document without including it in the relevant database referred to in subsection (a) of this section, nor shall any agency, in the future, issue a guidance document without including it in the relevant database. No agency may cite, use, or rely on guidance documents that are rescinded, except to establish historical facts. Within 240 days of the date on which OMB issues an implementing memorandum, an agency may reinstate a guidance document rescinded under this subsection without complying with any procedures adopted or imposed pursuant to section 4 of this order, to the extent consistent with applicable law, and shall include the guidance document in the relevant database.
- (c) The Director of OMB (Director), or the Director's designee, may waive compliance with subsections (a) and (b) of this section for particular guidance documents or categories of guidance documents, or extend the deadlines set forth in those subsections.
- (d) As requested by the Director, within 240 days of the date on which OMB issues an implementing memorandum under section 6 of this order, an agency head shall submit a report to the Director with the reasons for maintaining in effect any guidance documents identified by the Director.

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The Director shall provide such reports to the President. This subsection shall apply only to guidance documents existing as of the date of this order.

- **Sec. 4.** Promulgation of Procedures for Issuing Guidance Documents. (a) Within 300 days of the date on which OMB issues an implementing memorandum under section 6 of this order, each agency shall, consistent with applicable law, finalize regulations, or amend existing regulations as necessary, to set forth processes and procedures for issuing guidance documents. The process set forth in each regulation shall be consistent with this order and shall include:
 - (i) a requirement that each guidance document clearly state that it does not bind the public, except as authorized by law or as incorporated into a contract:
 - (ii) procedures for the public to petition for withdrawal or modification of a particular guidance document, including a designation of the officials to which petitions should be directed; and
 - (iii) for a significant guidance document, as determined by the Administrator of OMB's Office of Information and Regulatory Affairs (Administrator), unless the agency and the Administrator agree that exigency, safety, health, or other compelling cause warrants an exemption from some or all requirements, provisions requiring:
 - (A) a period of public notice and comment of at least 30 days before issuance of a final guidance document, and a public response from the agency to major concerns raised in comments, except when the agency for good cause finds (and incorporates such finding and a brief statement of reasons therefor into the guidance document) that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest:
 - (B) approval on a non-delegable basis by the agency head or by an agency component head appointed by the President, before issuance;
 - (C) review by the Office of Information and Regulatory Affairs (OIRA) under Executive Order 12866, before issuance; and
 - (D) compliance with the applicable requirements for regulations or rules, including significant regulatory actions, set forth in Executive Orders 12866, 13563 (Improving Regulation and Regulatory Review), 13609 (Promoting International Regulatory Cooperation), 13771 (Reducing Regulation and Controlling Regulatory Costs), and 13777 (Enforcing the Regulatory Reform Agenda).
- (b) The Administrator shall issue memoranda establishing exceptions from this order for categories of guidance documents, and categorical presumptions regarding whether guidance documents are significant, as appropriate, and may require submission of significant guidance documents to OIRA for review before the finalization of agency regulations under subsection (a) of this section. In light of the Memorandum of Agreement of April 11, 2018, this section and section 5 of this order shall not apply to the review relationship (including significance determinations) between OIRA and any component of the Department of the Treasury, or to compliance by the latter with Executive Orders 12866, 13563, 13609, 13771, and 13777. Section 4(a)(iii) and section 5 of this order shall not apply to pre-enforcement rulings.
- **Sec. 5**. *Executive Orders 12866, 13563, and 13609.* The requirements and procedures of Executive Orders 12866, 13563, and 13609 shall apply to guidance documents, consistent with section 4 of this order.
- **Sec. 6.** *Implementation.* The Director shall issue memoranda and, as appropriate, regulations pursuant to sections 3504(d)(1) and 3516 of title 44, United States Code, and other appropriate authority, to provide guidance regarding or otherwise implement this order.

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- Sec. 7. General Provisions. (a) Nothing in this order shall be construed to impair or otherwise affect:
 - (i) the authority granted by law to an executive department or agency, or the head thereof; or

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- (ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.
- (b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.
- (c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.
- (d) Notwithstanding any other provision in this order, nothing in this order shall apply:
 - (i) to any action that pertains to foreign or military affairs, or to a national security or homeland security function of the United States (other than guidance documents involving procurement or the import or export of non-defense articles and services);
 - (ii) to any action related to a criminal investigation or prosecution, including undercover operations, or any civil enforcement action or related investigation by the Department of Justice, including any action related to a civil investigative demand under 18 U.S.C. 1968;
 - (iii) to any investigation of misconduct by an agency employee or any disciplinary, corrective, or employment action taken against an agency employee;
 - (iv) to any document or information that is exempt from disclosure under section 552(b) of title 5, United States Code (commonly known as the Freedom of Information Act); or
 - (v) in any other circumstance or proceeding to which application of this order, or any part of this order, would, in the judgment of the head of the agency, undermine the national security.

And Samme

THE WHITE HOUSE, October 9, 2019.