November 17, 2020

THE DIRECTOR

M-21-06

MEMORANDUM FOR THE HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES

FROM: Russell T. Vought
         Director

SUBJECT: Guidance for Regulation of Artificial Intelligence Applications

Introduction

Executive Order 13859, "Maintaining American Leadership in Artificial Intelligence,"[1] requires the Director of the Office of Management and Budget (OMB), in coordination with the Director of the Office of Science and Technology Policy, the Director of the Domestic Policy Council, and the Director of the National Economic Council, to issue a memorandum that provides guidance to all Federal agencies to inform the development of regulatory and non-regulatory approaches regarding technologies and industrial sectors that are empowered or enabled by artificial intelligence (AI) and consider ways to reduce barriers to the development and adoption of AI technologies. Consistent with Executive Order 13859, OMB guidance on these matters seeks to support the U.S. approach to free markets, federalism, and good regulatory practices (GRPs), which has led to a robust innovation ecosystem. When considering regulations or policies related to AI applications, agencies should continue to promote advancements in technology and innovation, while protecting American technology, economic and national security, privacy, civil liberties, and other American values, including the principles of freedom, human rights, the rule of law, and respect for intellectual property.

Scope

This Memorandum sets out policy considerations that should guide, to the extent permitted by law, regulatory and non-regulatory approaches to AI applications developed and deployed outside of the Federal government. Although Federal agencies currently use AI in many ways to perform their missions, government use of AI is outside the scope of this Memorandum. While this Memorandum uses the definition of AI recently codified in statute,[2] it

---

[1] Exec. Order No. 13,859 of Feb. 11, 2019, Maintaining American Leadership in Artificial Intelligence, 84 Fed. Reg. 3967 (Feb. 14, 2019), *available at* https://www.whitehouse.gov/presidential-actions/executive-order-maintaining-american-leadership-artificial-intelligence/.

[2] Section 238(g) of the John S. McCain National Defense Authorization Act for Fiscal Year 2019, Pub. L. No. 115-232, 132 Stat. 1636, 1695 (Aug. 13, 2018) (codified at 10 U.S.C. § 2358, note), defines AI to include the following:

focuses on "narrow" (also known as "weak") AI, which goes beyond advanced conventional computing to learn and perform domain-specific or specialized tasks by extracting information from data sets, or other structured or unstructured sources of information.

This Memorandum is directed to the heads of all Executive Branch departments and agencies, including independent regulatory agencies.

Encouraging Innovation and Growth in AI

As stated in Executive Order 13859, "the policy of the United States Government [is] to sustain and enhance the scientific, technological, and economic leadership position of the United States in AI."[3] The deployment of AI holds the promise to improve efficiency, effectiveness, safety, fairness, welfare, transparency, and other economic and social goals, and America's continued status as a global leader in AI development is important to preserving our economic and national security. The importance of developing and deploying AI requires a regulatory approach that fosters innovation and growth and engenders trust, while protecting core American values, through both regulatory and non-regulatory actions and reducing unnecessary barriers to the development and deployment of AI.

To that end, Federal agencies must avoid regulatory or non-regulatory actions that needlessly hamper AI innovation and growth. Where permitted by law, when deciding whether and how to regulate in an area that may affect AI applications, agencies should assess the effect of the potential regulation on AI innovation and growth. While narrowly tailored and evidence-based regulations that address specific and identifiable risks could provide an enabling environment for U.S. companies to maintain global competitiveness, agencies must avoid a precautionary approach that holds AI systems to an impossibly high standard such that society cannot enjoy their benefits and that could undermine America's position as the global leader in AI innovation. Where AI entails risk, agencies should consider the potential benefits and costs of employing AI, as compared to the systems AI has been designed to complement or replace.

Furthermore, in the context of AI, as in other settings, agencies must consider the effect of Federal regulation on existing or potential actions by State and local governments. In some circumstances, agencies may use their authority to address inconsistent, burdensome, and duplicative State laws that prevent the emergence of a national market. Where a uniform

---

(1) Any artificial system that performs tasks under varying and unpredictable circumstances without significant human oversight, or that can learn from experience and improve performance when exposed to data sets.
(2) An artificial system developed in computer software, physical hardware, or another context that solves tasks requiring human-like perception, cognition, planning, learning, communication, or physical action.
(3) An artificial system designed to think or act like a human, including cognitive architectures and neural networks.
(4) A set of techniques, including machine learning, that is designed to approximate a cognitive task.
(5) An artificial system designed to act rationally, including an intelligent software agent or embodied robot that achieves goals using perception, planning, reasoning, learning, communicating, decision-making, and acting.
[3] *See* Exec. Order No. 13,859, § 1, 84 Fed. Reg. at 3967.

national standard for a specific aspect of AI is not essential, however, agencies should consider forgoing regulatory action.

Principles for the Stewardship of AI Applications

Consistent with law, agencies should take into consideration the following principles when formulating regulatory and non-regulatory approaches to the design, development, deployment, and operation of AI applications, both general and sector-specific. These principles, many of which are interrelated, reflect the goals and principles in Executive Order 13859. Agencies should calibrate approaches concerning these principles and consider case-specific factors to optimize net benefits.

Given that many AI applications do not necessarily raise novel issues, the following principles also reflect longstanding Federal regulatory principles and practices that are relevant to promoting the innovative use of AI. Promoting innovation and growth of AI is a high priority of the U.S. government. Fostering AI innovation and growth through forbearing from new regulation may be appropriate in some cases. Agencies should consider new regulation only after they have decided, in light of the foregoing section and other considerations, that Federal regulation is necessary.

1. *Public Trust in AI*

AI is expected to have a positive impact across many sectors of social and economic life, including employment, transportation, education, finance, healthcare, personal security, and manufacturing. At the same time, AI applications could pose risks to privacy, individual rights, personal choice, civil liberties, public health, safety, and security that must be carefully assessed and appropriately addressed. Since the continued adoption and acceptance of AI will depend significantly on public trust and validation, the government's regulatory and non-regulatory approaches to AI should contribute to public trust in AI by promoting reliable, robust, and trustworthy AI applications. For example, an appropriate regulatory approach that reduces accidents can increase public trust and thereby support the development of industries powered by AI. Regulatory approaches may also be needed to protect reasonable expectations of privacy on the part of individuals who interact with AI and to ensure that AI does not compromise the ability of individuals to make their own informed decisions. The appropriate regulatory or non-regulatory response to privacy and other risks must necessarily depend on the nature of the risk presented and the tools available to mitigate those risks.

2. *Public Participation*

In accordance with Executive Order 13563, "Improving Regulation and Regulatory Review," regulations "shall be adopted through a process that involves public participation."[4] Public participation, especially in those instances where AI uses information about individuals, will improve agency accountability and regulatory outcomes, as well as increase public trust and

---

[4] Exec. Order No. 13,563 of Jan. 18, 2011, Improving Regulation and Regulatory Review, § 2(a), 76 Fed. Reg. 3821 (Jan. 21, 2011), *available at* https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/inforeg/inforeg/eo12866/eo13563_01182011.pdf.

confidence. Agencies must provide ample opportunities for the public to provide information and participate in all stages of the rulemaking process, to the extent feasible and consistent with legal requirements (including legal constraints on participation to, for example, protect national security and address imminent threats or respond to emergencies). Agencies are also encouraged, to the extent practicable, to inform the public and promote awareness and widespread availability of voluntary frameworks or standards and the creation of other informative documents.

3. Scientific Integrity and Information Quality

The government's regulatory and non-regulatory approaches to AI applications should leverage scientific and technical information and processes. Agencies should hold information, whether produced by the government or acquired by the government from third parties, that is likely to have a clear and substantial influence on important public policy or private sector decisions (including those made by consumers) to a high standard of quality and transparency.[5] Consistent with the principles of scientific integrity in the rulemaking and guidance processes, agencies should articulate a clear public policy need when proposing a regulatory approach to AI and develop such approaches in a manner that both informs policy decisions and fosters public trust in AI. When an agency regulates AI applications, it should, as relevant, transparently articulate the strengths and weaknesses of the applications; intended optimizations or outcomes; bias and risk mitigations; potential impacts on competition, privacy and personal decision-making; any national security implications; and appropriate uses of the AI application's results.

4. Risk Assessment and Management

Regulatory and non-regulatory approaches to AI should be based on a consistent application of risk assessment and risk management across various agencies and various technologies. It is not necessary to mitigate every foreseeable risk; in fact, a foundational principle of regulatory policy is that all activities involve tradeoffs. Instead, a risk-based approach should be used to determine which risks are acceptable and which risks present the possibility of unacceptable harm, or harm that has expected costs greater than expected benefits. Agencies should be transparent about their evaluations of risk and re-evaluate their assumptions and conclusions at appropriate intervals so as to foster accountability. Correspondingly, the magnitude and nature of the consequences should an AI tool fail, or for that matter succeed, can help inform the level and type of regulatory effort that is appropriate to identify and mitigate risks. Specifically, agencies should follow the direction in Executive Order 12866, "Regulatory Planning and Review,"[6] to consider the degree and nature of the risks posed by various activities within their jurisdiction. Such an approach will, where appropriate, avoid hazard-based and unnecessarily precautionary approaches to regulation that could unjustifiably create

---

[5] To further ensure that agencies collect, use, and disseminate information that is fit for its intended purpose, OMB issued OMB M-19-15, Improving Implementation of the Information Quality Act (Apr. 24, 2019), *available at* https://www.whitehouse.gov/wp-content/uploads/2019/04/M-19-15.pdf. OMB M-19-15 clarified that Information Quality Act guidelines apply to current and future forms of AI if they are used—for example, to support a regulatory impact analysis—to create information disseminated by the Federal government.
[6] Exec. Order No. 12,866 of Sept. 30, 1993, Regulatory Planning and Review, 58 Fed. Reg. 51,735 (Oct. 4, 1993), *available at* https://www.reginfo.gov/public/jsp/Utilities/EO_12866.pdf.

anticompetitive effects or inhibit innovation.[7] Whenever practical and consistent with applicable law, agencies should seek to apply consistent risk assessment and risk management frameworks and approaches to similar AI functionalities across sectors. Any assessment of risk should compare that risk to risk presented by the situation that would obtain absent the AI application at issue; if an AI application lessens risk that would otherwise obtain, any relevant regulations presumably should permit that application.

5. Benefits and Costs

When developing regulatory and non-regulatory approaches, agencies will often consider the application and deployment of AI into already-regulated industries. Presumably, such significant investments would not occur unless they offered significant economic potential. As in all technological transitions of this nature, the introduction of AI may also create unique challenges. For example, while the broader legal environment already applies to AI applications, the application of existing law to questions of responsibility and liability for decisions made by AI could be unclear in some instances, leading to the need for agencies, consistent with their authorities, to evaluate the benefits, costs, and distributional effects associated with any identified or expected method for accountability. Executive Order 12866 calls on agencies to "select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity)."[8] Agencies should, when consistent with law, carefully consider the full societal costs, benefits, and distributional effects when considering regulations related to the development and deployment of AI applications. Such consideration will include the potential benefits and costs of employing AI, when compared to the systems AI has been designed to complement or replace; whether implementing AI will change the type of errors created by the system; and comparison to the degree of risk tolerated in other existing systems. In cases where a comparison to a current system or process is not available, evaluation of risks and costs of not implementing the system should be evaluated as well.

6. Flexibility

When developing regulatory and non-regulatory approaches, agencies should pursue performance-based and flexible approaches that are technology neutral and that do not impose mandates on companies that would harm innovation. Rigid, design-based regulations that attempt to prescribe the technical specifications of AI applications will in most cases be impractical and ineffective, given the anticipated pace with which AI will evolve and the resulting need for agencies to react to new information and evidence. Targeted agency conformity assessment schemes, to protect health and safety, privacy, and other values, will be essential to a successful, and flexible, performance-based approach. To advance American innovation, agencies should keep in mind international uses of AI, ensuring that American companies are not disadvantaged by the United States' regulatory regime.

---

[7] *See* Exec. Order No. 12,866, § 1(b)(5), 58 Fed. Reg. at 51,736 ("[E]ach agency shall consider incentives for innovation, consistency, predictability, [and] the cost of enforcement and compliance . . . to the government, regulated entities, and the public . . . .").
[8] *Id.* § 1(a).

7. Fairness and Non-Discrimination

Agencies should consider in a transparent manner the impacts that AI applications may have on discrimination. AI applications have the potential of reducing present-day discrimination caused by human subjectivity. At the same time, applications can, in some instances, introduce real-world bias that produces discriminatory outcomes or decisions that undermine public trust and confidence in AI or be used in other ways that violate anti-discrimination statutes. When considering regulations or non-regulatory approaches related to AI applications, agencies should consider, in accordance with law, issues of fairness and non-discrimination with respect to outcomes and decisions produced by the AI application at issue, as well as whether the AI application at issue may reduce levels of unlawful, unfair, or otherwise unintended discrimination as compared to existing processes.

8. Disclosure and Transparency

In addition to improving the rulemaking process, transparency and disclosure can increase public trust and confidence in AI applications by allowing (a) non-experts to understand how an AI application works and (b) technical experts to understand the process by which AI made a given decision. Such disclosures, when required, should be written in a format that is easy for the public to understand and may include identifying when AI is in use, for instance, if appropriate for addressing questions about how the application impacts human end users. Disclosures may be required to preserve the ability of human end users and other members of the public to make informed decisions, although agencies should be aware that some applications of AI could improve or assist human decision-making. Agencies should carefully consider the sufficiency of existing or evolving legal, policy, and regulatory environments before contemplating additional measures for disclosure and transparency. What constitutes appropriate disclosure and transparency is context-specific, depending on assessments of potential harms (including those resulting from the exploitation of disclosed information), the magnitude of those harms, the technical state of the art, and the potential benefits of the AI application.

9. Safety and Security

Agencies should promote the development of AI systems that are safe, secure, and operate as intended, and encourage the consideration of safety and security issues throughout the AI design, development, deployment, and operation process. Agencies should pay particular attention to the controls in place to ensure the confidentiality, integrity, and availability of the information processed, stored, and transmitted by AI systems. Agencies should also consider methods for providing systemic resilience, and for preventing bad actors from exploiting AI systems, including cybersecurity risks posed by AI operation, and adversarial use of AI against a regulated entity. When evaluating or developing regulatory and non-regulatory approaches to AI applications, agencies should be mindful of any potential safety and security risks and vulnerabilities, as well as the risk of possible malicious deployment and use of AI applications. Moreover, agencies should consider, where relevant, any national security implications raised by the unique characteristics of AI and AI applications and take actions to protect national security as appropriate for their authorities.

10. Interagency Coordination

A coherent and whole-of-government approach to AI oversight requires interagency coordination. Interagency coordination will be achieved under the auspices of Executive Order 12866, which governs the Office of Information and Regulatory Affairs (OIRA) in its oversight of Federal regulation and establishes principles of regulation that are relevant to this Memorandum. Consistent with Executive Order 12866, agencies should coordinate with each other to share experiences to ensure consistency and predictability of AI-related policies that advance American innovation and adoption of AI, while appropriately protecting privacy, civil liberties, national security, and American values and allowing sector- and application-specific approaches. When OIRA designates AI-related draft regulatory action as "significant" for purposes of interagency review under Executive Order 12866, OIRA will ensure that all agencies potentially affected by or interested in a particular action will have an opportunity to provide input.

Non-Regulatory Approaches to AI[9]

An agency may determine, after considering a particular AI application, that either existing regulations are sufficient or that the benefits of a new regulation do not justify its costs, at that time or in the foreseeable future. In these cases, the agency may consider either not taking any action or, instead, identifying non-regulatory approaches that may be appropriate to address the risk posed by certain AI applications. Examples of such non-regulatory approaches include:

- *Sector-Specific Policy Guidance or Frameworks.* Agencies should consider using any existing statutory authority to issue non-regulatory policy statements, guidance, or testing and deployment frameworks, as a means of encouraging AI innovation in that sector. Agencies should provide guidance where a lack of regulatory clarity may impede innovation. This may also include work done in collaboration with industry, such as development of playbooks and voluntary incentive frameworks.

- *Pilot Programs and Experiments.* Agencies should consider using any authority under existing law or regulation to grant waivers, deviations, and exemptions from regulations, or to allow pilot programs that provide safe harbors for specific AI applications. Such programs may also include events such as hackathons, tech sprints, challenges, and other types of piloting programs. As part of such programs, agencies may collect data on the design, development, deployment, operation, or outcomes of AI applications to improve their understanding of the benefits and risks, which could produce useful data to inform future rulemaking and non-regulatory approaches. If this information is of significant public interest, agencies should consider periodically informing the general public about emerging trends to help coordinate research efforts, new or emerging changes that will affect particular stakeholders (*e.g.*, consumers), and transparency about how specific AI applications generate net benefits and, if relevant, distributional effects. Any waivers, deviations, or exemptions granted by agencies should be consistent with the principles of this Memorandum.

---

[9] Appendix A provides technical guidance on rulemaking to inform the development of regulatory approaches to AI applications.

- *Voluntary Consensus Standards.* The private sector and other stakeholders may develop or participate in development of voluntary consensus standards that concern AI applications, which provide non-regulatory approaches to manage risks associated with AI applications that are potentially more adaptable to the demands of a rapidly evolving technology. Agencies must give a preference to voluntary consensus standards consistent with OMB Circular A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities."[10] In addition, agencies should consider relying on private-sector conformity assessment programs, credentialing, and related activities, before proposing either regulations or compliance programs. Whenever relying on work done by private sector or other stakeholders or collaborating with them, agencies must ensure that their actions do not contribute to entrenchment by market incumbents or erect barriers to entry.

- *Voluntary Frameworks*: Agencies should consider how to promote, leverage, or develop datasets, tools, frameworks, credentialing, and guidelines to accelerate understanding, innovation, and trust in AI. While some approaches may be designed specifically for AI systems, many existing frameworks—including those specific to safety, cybersecurity and privacy—have been developed with AI considerations in mind or are otherwise applicable to AI. Agencies should carefully consider what existing products can be used for particular AI needs and work with stakeholders if any gaps are identified to update existing datasets, tools, frameworks, credentialing, and guidelines or develop new ones, which could include risk management frameworks.

Reducing Barriers to the Deployment and Use of AI

As discussed above, Executive Order 13859 requires OMB to issue a memorandum to agencies that shall "consider ways to reduce barriers to the use of AI technologies in order to promote their innovative application while protecting civil liberties, privacy, American values, and United States economic and national security." Below are four non-exhaustive examples of actions agencies can take, outside the rulemaking process, to create an environment that facilitates the use and acceptance of AI.

Access to Federal Data and Models for AI R&D

Access to data (and metadata) can facilitate the innovative design, development, deployment, and operation of specific AI applications. Executive Order 13859 calls on agencies to increase public access to government data and models where appropriate. Increasing such access to government data must be done in a manner consistent with the Open, Public, Electronic, and Necessary Government Data Act;[11] OMB Circular No. A-130 "Managing

---

[10] Office of Mgm't & Budget, Exec. Office of the President, OMB Circular A-119, Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities (Jan. 27, 2016), *available at* https://www.whitehouse.gov/wp-content/uploads/2020/07/revised_circular_a-119_as_of_1_22.pdf.

[11] Pub. L. No. 115-435, tit. II, 132 Stat. 5534 (2019) (Title II of the Foundations for Evidence-Based Policymaking Act of 2018, also referred to as the "OPEN Government Data Act").

Information as a Strategic Resource";[12] OMB Memorandum M-13-13, "Open Data Policy-Managing Information as an Asset";[13] and other relevant authorities that require agencies to collect and create information in a way that supports public transparency as well as downstream, secondary information dissemination and processing by third parties, thereby making government information accessible, discoverable, and usable.

Agencies should also follow OMB guidance to agencies, pursuant to section 5 of Executive Order 13859, regarding discovery and usability of Federal data and models for non-Federal use. Agencies may also review their existing disclosure protocols to determine if it is appropriate to make more data public, as well as provide more granular data, rather than aggregate data. In increasing data access, agencies should not lose sight of the legal and policy requirements regarding the protection of sensitive information and vital public interests, such as privacy, security, and national economic competitiveness.[14]

Communication to the Public

The process by which agencies develop and implement regulatory and non-regulatory approaches to AI applications will have a significant impact on public perceptions of AI. Consistent with the principles described in this Memorandum, agencies should communicate with the public about the benefits and risks of AI in a manner that promotes public trust and understanding of AI. An important opportunity to do this is when publishing requests for information (RFIs) in the *Federal Register* that are related to AI. RFIs and similar notices can help ensure that public perceptions of AI are informed by agency risk assessments that are context-specific and based on sound scientific evidence. Agencies should communicate this information transparently by describing the underlying assumptions and uncertainties regarding expected outcomes, both positive and negative. For more specific guidance, agencies should consult OSTP's 2010 memorandum on scientific integrity when considering regulatory and non-regulatory approaches to AI.[15] Agencies are also encouraged to promote widespread availability of guidance documents and voluntary frameworks that may be created.[16]

---

[12] Office of Mgm't & Budget, Exec. Office of the President, OMB Circular No. A-130, Managing Information as a Strategic Resource (2013), *available at*
https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A130/a130revised.pdf.
[13] Office of Mgm't & Budget, Exec. Office of the President, OMB M-13-13, Open Data Policy: Managing Information as an Asset (2013), *available at*
https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2013/m-13-13.pdf.
[14] *See, e.g.*, Privacy Act of 1974 (codified at 5 U.S.C. § 552a); Trade Secrets Act (codified at 18 U.S.C. § 1905); Federal Information Security Modernization Act of 2014 (codified at 44 U.S.C. §§ 3551–3558); Confidential Information Protection and Statistical Efficiency Act of 2018 (codified at 44 U.S.C. § 3561–3853) (Title III of the Foundations for Evidence-Based Policymaking Act of 2018).
[15] John P. Holdren, Office of Sci. & Tech. Pol'y, Scientific Integrity (Dec. 17, 2010), *available at*
https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/scientific-integrity-memo-12172010.pdf.
[16] See Office of Mgm't & Budget, Exec. Office of the President, Final Bulletin for Agency Good Guidance Practices, 72 Fed. Reg. 3432 (Jan. 25, 2007), *available at*
https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/assets/regulatory_matters_pdf/012507_good_guidance.pdf.

Agency Participation in the Development and Use of Voluntary Consensus Standards and Conformity Assessment Activities

Executive Order 13859 calls for Federal engagement in the development of technical standards and related tools in support of reliable, robust, and trustworthy systems that use AI technologies. To promote innovation, use, and adoption of AI applications, standards could address many technical aspects, such as AI performance, measurement, safety, security, privacy, interoperability, robustness, trustworthiness, and governance. Moreover, Federal engagement with the private sector on the development of voluntary consensus standards will help agencies develop expertise in AI and identify practical standards for use in regulation. As directed by Executive Order 13859, the National Institute of Standards and Technology (NIST) developed a plan for Federal engagement in AI standards.[17] Agencies should use this plan to direct their involvement in AI standards development relevant to their authorities.

When engaging with private sector standard-setting organizations, agencies should adhere to OMB Circular A-119. Consistent with Section 12(d)(1) of the National Technology Transfer and Advancement Act of 1995, all Federal agencies must use voluntary consensus standards in place of government-unique standards in their procurement and regulatory activities, except where inconsistent with law or otherwise impractical.[18]

When appropriate, agencies may also leverage the work of standards bodies and independent organizations that have extensive experience in managing conformity assessment programs and who have conformity assessment or certification programs in AI. Conformity assessment procedures provide a means of enhancing the confidence that the products, services, systems, persons, or bodies have specifically required characteristics, and that these characteristics are consistent from product to product, service to service, system to system, and in similar scenarios. Agencies should rely on the guidance in NIST publications to understand conformity assessment concepts[19] and to use conformity assessment in an effective and efficient manner that meets agency requirements.[20]

International Regulatory Cooperation

Executive Order 13609, "Promoting International Regulatory Cooperation," calls on the Regulatory Working Group, which was established by Executive Order 12866, to consider "appropriate strategies for engaging in the development of regulatory approaches through

---

[17] Nat'l Inst. of Standards & Tech., U.S. Dep't of Commerce, U.S. Leadership in AI: A Plan for Federal Engagement in Developing Technical Standards and Related Tools (Aug. 9, 2019), *available at* https://www.nist.gov/topics/artificial-intelligence/plan-federal-engagement-developing-ai-technical-standards-and-related.

[18] *See* Pub. L. No. 104-113, § 12(d), 110 Stat. 775, 783 (1996) (as codified at 15 U.S.C. § 272, note).

[19] Lisa Carnahan & Amy Phelps, Nat'l Inst. of Standards and Tech., U.S. Dep't of Commerce, ABC's of Conformity Assessment, NIST Special Pub. 2000-01 (Sept. 2018), *available at* https://doi.org/10.6028/NIST.SP.2000-01.

[20] Lisa Carnahan & Amy Phelps, Nat'l Inst. of Standards and Tech., U.S. Dep't of Commerce, Conformity Assessment Considerations for Federal Agencies, NIST Special Pub. 2000-02 (Sept. 2018), *available at* https://doi.org/10.6028/NIST.SP.2000-02.

international regulatory cooperation, particularly in emerging technology areas."[21] Accordingly, agencies should engage in dialogues to promote compatible regulatory approaches to AI and to promote American AI innovation, while protecting privacy, civil rights, civil liberties, and American values. Such discussions, including those with the general public, can provide valuable opportunities to share best practices, data, and lessons learned, and ensure that America remains at the forefront of AI development. They can also minimize the risk of unnecessary regulatory divergences from risk-based approaches implemented by key U.S. trading partners. In addition, agencies should consider existing international frameworks to which the United States has committed itself and the development of strategic plans for coordination and cooperation with international partners.

Agency Plans to Achieve Consistency with this Memorandum

Executive Order 13859 requires that implementing agencies with regulatory authorities review their authorities relevant to AI applications and submit plans to OMB on achieving consistency with this Memorandum.

The agency plan must identify any statutory authorities specifically governing agency regulation of AI applications, as well as collections of AI-related information from regulated entities. For these collections, agencies should describe any statutory restrictions on the collection or sharing of information (*e.g.*, confidential business information, personally identifiable information, protected health information, law enforcement information, and classified or other national security information). The agency plan must also report on the outcomes of stakeholder engagements that identify existing regulatory barriers to AI applications and high-priority AI applications that are within an agency's regulatory authorities. OMB also requests agencies to list and describe any planned or considered regulatory actions on AI. Appendix B provides a template for agency plans.

Agency plans are due on May 17, 2021 and should be submitted to OIRA at the following email address: **AIplans@omb.eop.gov**. To inform the public of each agency's planned and implemented activities, agency plans must be posted on, or be accessed from (through a URL redirect) the following domain on the agency's website: **www.[agencyname].gov/guidance**.

---

[21] Exec. Order 13,609 of May 1, 2012, Promoting International Regulatory Cooperation, § 2(ii)(A), 77 Fed. Reg. 26,413, 26,413 (May 4, 2012), *available at* https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/inforeg/inforeg/eo_13609/eo13609_05012012.pdf.

Appendix A: Technical Guidance on Rulemaking

Consistent with applicable law and Executive Order 12866, before deciding to regulate, an agency must first identify the problem it seeks to address and consider whether regulation is justified or if non-regulatory approaches are appropriate. This process will often begin by assessing the adequacy of existing regulation at a Federal, State, or local level, as well as potential actions by private parties.

In considering regulatory and non-regulatory approaches to the development and deployment of AI, it is important to recognize the unique characteristics of AI. For example, while the rapid emergence of new paradigms can foster innovation that the government should not hinder, the pace of AI development and application will challenge agencies to develop regulatory and non-regulatory approaches that are adaptable. In addition, current technical challenges in creating interpretable AI can make it difficult for agencies to ensure a level of transparency necessary for humans to understand the decision-making of AI applications. The following discussion of various technical aspects of the regulatory process will help agencies address the unique aspects of the rapidly changing AI landscape.

Regulatory Impact Analysis

A regulatory analysis should begin with a clear explanation of the need for the regulatory action, including a description of the problem that the agency seeks to address. For example, agencies should explain whether the action is intended to address a market failure (*e.g.*, asymmetric information), clarify uncertainty related to existing regulations, or address another factor, such as protecting privacy or civil liberties, preventing unlawful discrimination, or advancing the United States' economic and national security. In the case of AI, a regulatory impact analysis supporting a proposed regulatory approach should articulate a clear public policy need for Federal regulation. Often, in order to pursue the larger goals of Executive Order 13859, agencies should consider whether a change in regulatory policy is needed due to the adoption of AI applications in an already regulated industry, or due to the development of substantially new industries facilitated by AI.

In addition, agencies should "consider how best to promote retrospective analysis of rules that may be outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them in accordance with what has been learned," in accordance with Executive Order 13563.[22] In conducting such retrospective reviews, agencies can determine whether regulatory changes are necessary to remove barriers to the adoption of net beneficial AI systems by identifying and promulgating deregulatory actions, consistent with Executive Orders 13771, "Reducing Regulation and Controlling Regulatory Costs,"[23] and 13777, "Enforcing the Regulatory Reform Agenda."[24] To inform these efforts, agencies should develop mechanisms

---

[22] Exec. Order No. 13,563 of Jan. 18, 2011, Improving Regulation and Regulatory Review, § 6(a), 76 Fed. Reg. 3821, 3822 (Jan. 21, 2011), *available at* https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/inforeg/inforeg/eo12866/eo13563_01182011.pdf.

[23] Exec. Order No. 13,771 of Jan. 13, 2017, Reducing Regulation and Controlling Regulatory Costs, 82 Fed. Reg. 9339 (Feb. 3, 2017), *available at* https://www.govinfo.gov/content/pkg/FR-2017-02-03/pdf/2017-02451.pdf.

[24] Exec. Order No. 13,777 of Feb. 24, 2017, Enforcing the Regulatory Reform Agenda, 82 Fed. Reg. 12,285 (Mar. 1, 2017), *available at* https://www.govinfo.gov/content/pkg/FR-2017-03-01/pdf/2017-04107.pdf.

for industry to seek guidance and/or request clarification about regulations that may be creating uncertainty around the use of AI. Such mechanisms should enable industry to request information about how an agency may interpret existing regulations and/or statutory authorities related to the use of AI.

After identifying a set of potential regulatory approaches, the agency should conduct a benefit-cost analysis that estimates the benefits and costs associated with each alternative approach. The benefits and costs should be quantified and monetized to the extent possible and appropriate, and presented in both physical units (*e.g.*, number of accidents avoided) and monetary terms. When quantification of a particular benefit or cost is not possible, it should be described qualitatively. The analysis of these alternatives should also evaluate, where relevant and appropriate and consistent with Executive Order 13859, impacts to equity, human dignity, fairness, potential distributive impacts, privacy and civil liberties, personal freedom, and other American values. The agency's analysis should be based on the best available scientific, technical, and economic information. Agencies should rely on OMB Circular A-4, "Regulatory Analysis," for more technical guidance.[25]

Public Consultation

The informal rulemaking process under the Administrative Procedure Act provides predictable and meaningful opportunities for interested stakeholders to provide input on draft regulations and scrutinize the evidence and analytic bases of regulatory proposals. In soliciting public input on Notices of Proposed Rulemaking (NPRMs) that relate to AI applications, agencies will benefit from the perspectives and expertise of stakeholders engaged in the design, development, deployment, operation, and impact of AI applications, and facilitate a decision-making process that is more transparent and accountable.

To the extent feasible, agencies should also provide opportunities for stakeholder consultation before the NPRM stage, including through the issuance, when appropriate, of RFIs and Advance Notices of Proposed Rulemaking (ANPRMs) to inform decisions about the need to regulate. Agencies should also consider holding stakeholder and public meetings both prior to issuing an NPRM and during the public comment period.

Assessing Risk

When humans delegate decision-making and other functions to AI applications, there is a risk that AI's pursuit of its defined goals may diverge from the underlying or original human intent and cause unintended consequences—including those that negatively impact privacy, civil rights, civil liberties, confidentiality, security, and safety. Because traditional forms of delegated decision-making are accompanied by risks that present some—although not all—of the dynamics present in the case of delegation to AI, existing approaches to risk continue to be relevant. However, the kind of AI adopted and the way it works in decision-making may present new demands on existing risk frameworks. In addition, because components of AI applications, such as algorithms or the data they are trained on and use, may be sensitive or subject to legal

---

[25] Office of Mgm't & Budget, Exec. Office of the President, OMB Circular A-4, Regulatory Analysis (Sept. 17, 2003), *available at* https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf.

protections (*e.g.*, privacy or intellectual property), agencies should consider the risks of inadequate protections to algorithms and data throughout the design, development, deployment, and operation of an AI system, given the level of sensitivity of the algorithms and data. Agencies should also consider that an AI application could be deployed in a manner that yields anticompetitive effects that favors incumbents at the expense of new market entrants, competitors, or up-stream or down-stream business partners.

Managing Risk

The management of risks created by AI applications should be appropriate to, and commensurate with, the degree of risk that an agency determines in its assessment. In general, as emphasized above, the agencies should also be comparing risks unique to the AI application to other similar risks associated with not using such applications within a regulatory framework or risks mitigated by the adoption of AI. For AI applications, agencies should adopt a tiered approach in which the degree of risk and consequences of both success and failure of the technology determines the regulatory approach, including the option of not regulating. Agencies should be aware that there is always likely to be at least some risk, including that associated with not knowing what is currently unknown. For AI applications that pose lower risks, agencies can rely on less stringent and burdensome regulatory approaches—or non-regulatory approaches— such as requiring information disclosures or consumer education. For higher risk AI applications, agencies should consider, for example, the effect on individuals, the environments in which the applications will be deployed, the necessity or availability of redundant or back-up systems, the system architecture or capability control methods available when an AI application makes an error or fails, and how those errors and failures can be detected and remediated.

Appendix B: Template for Agency Plans

Agency	
1. Statutory Authorities Directing or Authorizing Agency Regulation of AI Applications. List and describe any statutes that direct or authorize your agency to issue regulations specifically on the development and use of AI applications.	
Statute	**Brief Description**
2. Active Collections of AI-Related Information. List and describe any of your agency's collections of information approved by OMB under the Paperwork Reduction Act that relate directly to the design, development, deployment, and operation of AI applications in the private sector, including if there are any statutory or regulatory restrictions on the use or sharing of this information.	
Title/OMB Control Number	**Brief Description**
3. AI Use Case Priorities. Informed by stakeholder engagement, list and describe AI applications that are within your agency's regulatory authorities.	
AI use case	**Brief Description**

4. **AI Regulatory Barriers**. Informed by stakeholder engagement, list and describe existing processes, policies, or regulations that inhibit development or commercialization of AI applications within your agency's authority.	
Process, policy, or regulation	**Brief description**

5. **Planned Regulatory Actions Concerning AI Applications**. List and describe any planned or considered regulatory actions and provide, to the extent possible, information about the agency's consideration of the principles and approaches described in OMB Memorandum M-21-06.	
Regulatory Action	**Brief description**