U.S. DEPARTMENT OF AGRICULTURE
WASHINGTON, D.C. 20250

DEPARTMENTAL REGULATION	Number: DR 1074-001
SUBJECT: Scientific Integrity	DATE: November 18, 2016
	OPI: Office of the Chief Scientist

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1. PURPOSE

This Departmental Regulation (DR) establishes the U.S. Department of Agriculture's (USDA) Scientific Integrity Policy and provides instruction and guidance to Departmental leadership and employees to ensure the highest level of integrity in all aspects of the Department's and USDA agencies' involvement with scientific and technological processes, research, analyses, and products. This DR includes instructions and guidance for decision makers as they develop public policies that are informed by science relevant to food, agriculture, natural resources, rural development, and related issues. This DR is intended to instill public confidence in USDA research and science-based public policymaking by articulating the principles of scientific integrity and the roles and responsibilities of all USDA employees, including career staff and political appointees, in upholding these principles.

2. SPECIAL INSTRUCTIONS/CANCELLATION

a. This regulation supersedes DR 1074-001 ("Scientific Integrity"), dated May 10, 2013, and rescinds DR 2401-001 ("USDA Intramural Research Misconduct Policies and Guidelines"), dated June 18, 2008, the "USDA Scientific Integrity Policy Handbook,"

dated July 10, 2013, and the "USDA Scientific Integrity Review Panel (SIRP) Guidelines," dated May 2015.

b. Relative to the previously issued version of DR 1074-001 and associated guidance, this updated DR 1074-001:

(1) Incorporates additional clarifications and provisions to ensure and promote scientific integrity in Departmental and USDA agency activities;

(2) Implements more robust and well-defined procedures for responding to allegations of compromised scientific integrity;

(3) Harmonizes the procedures previously used for responding to alleged violations of the USDA Scientific Integrity Policy with those used for responding to allegations of research misconduct made against USDA employees (*see* Departmental Manual (DM) 1074-001 "Procedures for Responding to Allegations of Compromised Scientific Integrity"); and

(4) Clarifies the roles of the USDA Chief Scientist, Departmental Scientific Integrity Officer (DSIO), and Agency Scientific Integrity Officers (ASIOs) in overseeing Departmental and USDA agency responses to allegations of compromised scientific integrity.

3. APPLICABILITY AND SCOPE

a. This DR applies to:

(1) All USDA mission areas, agencies, and offices.

(2) All USDA employees, political and career, who:

(a) Engage in, supervise, manage, or report on scientific activities (*see* Section 9bb);

(b) Analyze and/or publicly communicate information resulting from scientific activities; and/or

(c) Utilize information derived from scientific activities in policy and decision making.

b. All contractors, cooperators, partners, permittees, lessees, grantees, and volunteers, who engage or assist in the activities identified in Section 3a(2)(a) through (c) on behalf of USDA, are expected to uphold the principles of scientific integrity established by this DR. However, any express requirements will be set forth in individual agreements, contracts, statements of work, memoranda of understanding, etc., and/or established via issuance of a separate rule or other Departmental policy. ***NOTE:*** *Research institutions that receive*

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allegations of research misconduct involving USDA-funded extramural research should refer to Title 2 of the Code of Federal Regulations (CFR) Part 422 ("Research Institutions Conducting USDA-Funded Extramural Research; Research Misconduct").

4. BACKGROUND

a. On December 6, 2000, the White House Office of Science and Technology Policy (OSTP) published the *Federal Policy on Research Misconduct* in the Federal Register (65 FR 76260). The purpose of this Federal Government-wide policy was to enhance consistency in the responses to allegations of research misconduct that pertain to research conducted or supported by the Federal Government. The policy established: (1) a Federal-wide definition of research misconduct; (2) criteria required for making a finding of research misconduct; (3) a multi-phase process for responding to allegations of research misconduct; and (4) guidelines for safeguarding the interests of informants and the subjects of allegations. The policy directed Federal departments and agencies that conduct or support research to implement the policy.

b. On March 9, 2009, a Presidential memorandum on "Scientific Integrity" was issued to the Heads of Federal departments and agencies. This memorandum emphasized that the public must be able to trust the science and scientific process used to inform public policy decisions. As a follow-up to the Presidential memorandum, OSTP issued a memorandum, dated December 17, 2010, directing Federal departments and agencies to develop and implement scientific integrity policies addressing the following: (1) the foundations of scientific integrity; (2) the public communication of scientific and technological findings; (3) the use of Federal Advisory Committees (FACs) tasked with providing scientific advice; and (4) the professional development of Federal Government scientists and engineers.

c. On September 30, 1993, Presidential Executive Order (E.O.) 12866, titled "Regulatory Planning and Review," was issued. This E.O. directed Federal agencies to base their regulatory decisions on "the best reasonably obtainable scientific, technical, economic, and other information" concerning the need for, and consequences of, intended regulations. On January 18, 2011, E.O. 13563, titled "Improving Regulation and Regulatory Review," was issued. Section 5 of this E.O. indicated that "[c]onsistent with the President's Memorandum for the Heads of Executive Departments and Agencies, 'Scientific Integrity' (March 9, 2009), and its implementing guidance, each agency shall ensure the objectivity of any scientific and technological information and processes used to support the agency's regulatory actions." As further explained in a memorandum (No. M-11-10) issued by the Office of Management and Budget on February 2, 2011, E.O. 13563 extends the President's 2009 Memorandum on "Scientific Integrity" to agency use of scientific and technological information relied upon to support regulatory actions.

d. This DR is issued in response to, and is consistent with, the *Federal Policy on Research Misconduct*, the 2009 Presidential Memorandum on "Scientific Integrity," and the 2010 OSTP Memorandum on "Scientific Integrity."

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5. REFERENCES

a. As applicable, this DR should be used in conjunction with:

(1) DM 1074-001, Procedures for Responding to Allegations of Compromised Scientific Integrity
(2) 5 United States Code (U.S.C.) 301, Departmental Regulations
(3) 7 CFR 2.21(a)(11), Delegations of Authority to the Under Secretary for Research, Education, and Economics Related to Scientific Integrity
(4) 7 CFR 2.69, Establishment of the Office of the Chief Scientist
(5) Public Law (PL) 106-554, Section 515, The Information Quality Act
(6) Office of Management and Budget (OMB) Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies, 2002
(7) OMB Final Information Quality Bulletin for Peer Review, 2004
(8) PL 103-354, Federal Crop Insurance Reform and Department of Agriculture Reorganization Act of 1994
(9) Statistical Policy Directive No. 1: Fundamental Responsibilities of Federal Statistical Agencies and Recognized Statistical Units
(10) Statistical Policy Directive No. 3: Compilation, Relevance, and Evaluation of Principal Federal Economic Indicators
(11) Statistical Policy Directive No. 4: Release and Dissemination of Statistical Products Produced by Federal Statistical Agencies
(12) 65 FR 76260-76264, Federal Policy on Research Misconduct
(13) 2 CFR 422, Research Institutions Conducting USDA-Funded Extramural Research; Research Misconduct
(14) PL 101-12, Whistleblower Protection Act (WPA) of 1989
(15) PL 112-199, Whistleblower Protection Enhancement Act (WPEA) of 2012
(16) 5 U.S.C. Appendix 2, Federal Advisory Committee Act of 1972
(17) DR 1041-001, Advisory Committee Management
(18) DR 1410-001, Publications Review/Clearance Policy
(19) DR 1495-001, New Media Roles, Responsibilities, and Authorities
(20) 5 CFR 735, Employee Responsibilities and Conduct
(21) 5 CFR 2635, Standards of Ethical Conduct for Employees of the Executive Branch
(22) DR 4070-735-001, Employee Responsibilities and Conduct
(23) Ethics Issuance No. 09-1, Ethics Issues Related to USDA Scientists

b. This DR shall not be interpreted to conflict with the rights of an employee under the law, including:

(1) The Federal Service Labor-Management Relations Statute (5 U.S.C. 7101-7135);
(2) Applicable collective bargaining agreements;
(3) Those provisions of Chapter 75 of Title 5 of U.S.C. relating to disciplinary action of employees;

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(4) The WPA of 1989; and
(5) The WPEA of 2012.

c. Additionally, this DR shall not be interpreted to conflict with any rights accorded a union representative under the Federal Service Labor-Management Relations Statute when communicating as a union representative. Further, it is recognized that the implementation of this DR may be subject to collective bargaining, the results of which may modify the policy and/or procedures stated or implied herein.

6. POLICY

Pursuant to the *Federal Policy on Research Misconduct*, the 2009 Presidential Memorandum on "Scientific Integrity," the 2010 OSTP Memorandum on "Scientific Integrity," and in accordance with applicable statutes, regulations, trade agreements, and/or international protocols, Executive Orders, or Presidential Memoranda, the policy of the Department is to:

a. Promote a culture of scientific integrity. Science, and public trust in science, thrives in an environment that shields scientific data and analyses and their use in policymaking from political interference or inappropriate influence. Scientific findings and products must not be suppressed or altered for political purposes and must not be subjected to inappropriate influence.

b. Select and retain candidates for scientific and technical positions at USDA based on the candidate's scientific and technical knowledge, credentials, experience, and integrity, and hold them and their supervisors to the highest standard of professional and scientific ethics, including those described in the USDA Code of Scientific Ethics (Appendix A).

c. Ensure the quality, accuracy, and transparency of scientific information used to support policy and decision making, including to:

(1) Use scientific information that is derived from well-established scientific processes;

(2) Ensure that scientific data and research used to support policy decisions undergo independent peer review by qualified experts, where feasible and appropriate, and consistent with law;[1]

(3) Reflect scientific information appropriately and accurately;[2] and

[1] *See* OMB Final Information Quality Bulletin for Peer Review, 2004 (available at http://www.whitehouse.gov/sites/default/files/omb/assets/omb/memoranda/fy2005/m05-03.pdf).

[2] *See* OMB Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies, 2002 (available at http://www.whitehouse.gov/sites/default/files/omb/assets/omb/fedreg/reproducible2.pdf).

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(4) Make scientific findings or conclusions considered or relied on in policy decisions publicly available online and in open formats, to the extent practicable, consistent with the Administration's Open Government Initiative, the Freedom of Information Act, the Administrative Procedure Act, and other applicable statutes, regulations or document-handling procedures and policies. Where feasible and appropriate, the following will also be provided: information on the specific approach, data, and models used to develop such scientific conclusions, including a clear explanation of underlying assumptions and uncertainties; and, where appropriate, probabilities associated with a range of projections or scenarios.

d. Continue to develop policies, in coordination with the General Services Administration and consistent with the Administration's guidance on lobbyists serving on FACs, for convening FACs tasked with giving scientific advice, consistent with the following:

(1) The recruitment process for new FAC members should be as transparent as practicable. When practicable and appropriate, FAC member vacancies will be announced widely, including notification in the Federal Register with an invitation for the public to recommend individuals for consideration and for self-nominations;

(2) Professional biographical information of FAC appointees (including current and past affiliations) will be made widely available to the public (e.g., via a Web site) subject to the Privacy Act and other statutory/regulatory considerations. The information should clearly illustrate the appointees' qualifications for serving on the committee;

(3) The selection of members to serve on a scientific or technical FAC will be based on expertise, knowledge, and contribution to the relevant subject area. Additional factors for consideration will include the availability of the member to serve, diversity among members of the FAC, and the ability to work effectively on advisory committees. Committee membership should be fairly balanced in terms of points of view represented with respect to the functions to be performed by the FAC;

(4) Except when prohibited by law, USDA will make all Conflict of Interest waivers granted to the committee members publicly available; and

(5) Except when explicitly stated in a prior agreement between USDA and a FAC, all reports, recommendations, and products produced by FACs will be treated as solely the findings of such committees rather than of the U.S. Government, and thus, will not be subjected to intra- or inter-agency revision.

(6) FAC reports, recommendations, and other products are strictly advisory. The Department and USDA agencies are not obligated to implement committee scientific recommendations.

e. Facilitate the free flow of scientific and technological information, and support scientific integrity in the communication of scientific findings and products. The facilitation of the dissemination of scientific and technological information will be to the extent allowed by,

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and consistent with, privacy and classification standards, as well as with other applicable policies[3] and guidelines for communicating scientific information responsibly.

(1) Accordingly, it is the policy of the Department to:

(a) Encourage, but not require, USDA scientists to participate in communications with the media regarding their scientific findings (data and results). Scientists should coordinate media queries or opportunities (e.g., requests for interviews, requests for submissions of written commentary, etc.) with their immediate supervisors and public affairs offices in accordance with the applicable policies of their respective agencies/staff offices. Agencies are expected to coordinate with the Office of Communications (OC), which provides a centralized operational direction for communications about the work of the Department. The Office of Communications' role in communications regarding research and analysis done by USDA scientists is to assist with presentation, style, and logistics of the communications, and to advise on potential media requests or media outreach strategies. USDA agencies and staff offices may also identify and offer knowledgeable spokespersons, other than the scientist who originally received the media query, to respond to the query in an objective, non-partisan, and articulate manner.

(b) Ensure that the work and views of USDA scientists are accurately represented in USDA media communications.

(c) Ensure that USDA scientists may communicate their scientific findings (data and results) objectively without political interference or inappropriate influence, while at the same time complying with USDA policies and procedures for planning and conducting scientific activities, reporting scientific findings, and reviewing and releasing scientific products. Scientific communications for non-USDA media (e.g., manuscripts and presentations for scientific journals, workshops, conferences, and symposia) should adhere to agency technical review procedures.

1 When reporting scientific findings or communicating with the media or the public in their official capacities as USDA employees, USDA scientists should refrain from making or publishing statements that could be construed as being judgments of, or recommendations on, USDA or any other Federal Government policy, unless they have secured appropriate prior approval to do so. Such communications should remain within the bounds of their scientific or technological findings, unless otherwise authorized.

2 When communicating with the media or the public in their personal capacities, USDA scientists may express their personal views and opinions; however, they should not claim to officially represent the Department or its

[3] For example, the United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern, issued March 29, 2012, and the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern, issued September 24, 2014.

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policies, or use the Department or other U.S. Government seals or logos. Personal or private activities may not violate Federal ethics rules.

(2) USDA officials, including public affairs officers, may not direct USDA scientists and technology experts to alter scientific and technological research findings for political or public relations purposes.

(3) USDA officials, including public affairs officers, may neither ask nor suggest that USDA scientists and technology experts alter the presentation of their scientific findings in a manner that may compromise the objectivity or accurate representation of those findings.

(4) The provisions in this DR are not meant to limit the obligations of political appointees and agency leadership in setting research priorities or the priorities of other scientific activities. The provisions in this DR are also not intended to limit the ability of USDA public affairs staff to make decisions about whether or not the Department issues press releases or other external communications vehicles about research findings and other scientific activities.

f. Encourage USDA scientists and other USDA employees involved in USDA scientific activities to interact with the broader scientific community, in a manner that is consistent with Federal rules of ethics, job responsibilities, and existing agency policies, and to the extent that is practicable given the availability of funding to support such interactions and any budgetary restraints. This includes:

(1) Encouraging publication of research findings in peer-reviewed, professional, or scholarly journals;

(2) Encouraging presentation of research findings at professional meetings;

(3) Allowing service on editorial boards or as editors of professional or scholarly journals;

(4) Allowing participation in professional societies, committees, task forces, and other specialized bodies of professional societies, including removing barriers to serving as officers or on governing boards of such societies, to the extent allowed by law; and

(5) Allowing honors and awards to be received for contributions to scientific activities, discoveries, and products with the goal of minimizing, to the extent practicable, disparities in the potential for private-sector and public-sector scientists and engineers to accrue the professional recognition of such honors or awards.

NOTE: *USDA employees who have general questions about financial conflicts of interest, Federal criminal ethics statutes, the Ethics in Government Act (5 USC App. 4), and the executive branch-wide Standards of Ethical Conduct (5 CFR Part 2635), should seek advice and guidance from USDA's Office of Ethics (OE) at DAEO.ethics@oe.usda.gov.*

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g. Ensure that mechanisms are in place to respond to allegations of compromised scientific integrity. *See* Section 8 and DM 1074-001.

h. Protect from prohibited personnel practices (as defined in 5 U.S.C. 2302(b)) those USDA employees who uncover and report allegations of compromised scientific integrity in good faith, as well as those USDA employees alleged to have compromised scientific integrity in the absence of a finding that the individual compromised scientific integrity.

i. Continue to comply with the requirements of the WPA of 1989, and its expanded protections enacted by PL 103-424 and the WPEA of 2012. The USDA shall also continue to comply with all Department- and agency-specific WPA regulations, rules, and policies.

   (1) USDA employees, former USDA employees, and applicants for USDA employment who make allegations of compromised scientific integrity consistent with the WPA of 1989 and the WPEA of 2012 may seek redress for retaliation as provided under these Acts. Those individuals who believe they have been improperly retaliated against may contact the USDA Office of Inspector General (OIG), the USDA Whistleblower Protection Ombudsman, and/or the U.S. Office of Special Counsel.

j. Prohibit the compromise of scientific integrity, including research misconduct. *See* Sections 9z and 9dd(1).

7. RESPONSIBILITIES

a. As the USDA Chief Scientist, the Under Secretary for USDA's Research, Education and Economics (REE) Mission Area will oversee all aspects of this DR and have oversight authority for USDA proceedings to review and resolve allegations of compromised scientific integrity. Specific responsibilities, which may be delegated as appropriate, include:

   (1) Providing leadership for the Department on scientific integrity.

   (2) Ensuring Departmental compliance with this DR and DM 1074-001 for responding to allegations of compromised scientific integrity.

   (3) Seeking consultation with the USDA Science Council in regard to implementation of this DR.

   (4) Reviewing USDA mission area, agency, and office compliance with this DR.

   (5) Updating this DR and any accompanying guidance, as appropriate.

   (6) Designating the duties of the DSIO to a senior career staff person with scientific or scholarly credentials or both.

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b. The DSIO will:

(1) Serve as the primary Department-level contact for questions regarding the policies of this DR.

(2) Develop training and conduct outreach activities to facilitate USDA employee awareness and understanding of the policies of this DR.

(3) Serve as the Scientific Integrity Officer for the Office of the Secretary.

(4) Serve as a neutral point of contact (ombudsman) for receiving allegations of compromised scientific integrity that are made against USDA employees through the OIG hotline, directly from the public, or from other sources.

(5) Refer allegations of compromised scientific integrity, if received by the DSIO, to the appropriate ASIO within 5 days of receipt, unless the ASIO is the individual alleged to have compromised scientific integrity or has an identified conflict of interest.

(6) Provide oversight of Departmental and agency responses to allegations of compromised scientific integrity referred for an inquiry or investigation, including:

(a) Reviewing ASIO-submitted reports of allegations and their disposition; and

(b) Maintaining a status report of responses to allegations as a means of monitoring the progress toward resolution.

(7) Serve as, and fulfill the responsibilities of, the USDA Research Integrity Officer (USDA RIO) as described in 2 CFR 422 ("Research Institutions Conducting USDA-Funded Extramural Research; Research Misconduct").

(8) Coordinate with the Office of the General Counsel (OGC), OIG, the Office of Ethics, the Office of Human Resources Management, OC, the Office of the Chief Information Officer, and other offices, as necessary, to ensure that scientific integrity-related policies are aligned and guidance is appropriate and consistent.

(9) Report any potentially criminal behavior to OIG that is uncovered during the course of responding to an allegation of compromised scientific integrity, and coordinate with the appropriate USDA entity to ensure that all records, documents, or other materials related to the allegation are provided to OIG.

(10) Keep the Chief Scientist and the Science Council informed on the status of the implementation of this DR and any compliance concerns, as warranted.

(11) Maintain a publicly accessible Web site with the following or a link to the following:

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(a) This DR.

(b) Procedures for reporting and responding to allegations of compromised scientific integrity.

(c) Contact information for the DSIO and ASIOs.

(d) A summary of closed scientific integrity cases involving formal allegations referred for an inquiry or investigation. The summary will include a description of the nature and disposition of the allegations.

c. Assistant Secretaries and Under Secretaries will:

(1) Ensure that their agencies and staff offices comply with this DR and DM 1074-001.

(2) Ensure that applicable USDA mission area, agency, and staff office policies and guidance are consistent with this DR.

d. USDA Agencies will:

(1) Implement this DR as it pertains to their agency.

(2) Develop agency-specific scientific integrity policies and guidance, as appropriate and necessary, including appropriate language in contracts, grants, permits, leases, and cooperative agreements.

(3) Coordinate, as necessary, with the appropriate employee relations and labor management staff, ethics officer, information integrity officer, peer review officer, public affairs officer, the DSIO, advisory committee Designated Federal Officers, contracting and grant personnel, and others to ensure that agency policies and guidance are consistent with this DR.

(4) Ensure that agency employees, who are covered by the scope of this DR, are aware of the policies in the DR and the procedures for reporting allegations of compromised scientific integrity.

(5) Provide agency employees, who are covered by the scope of this DR, with any necessary guidance and training to understand and fulfill their responsibilities under this DR and any agency-specific guidance on scientific integrity.

(6) Ensure that contractors, cooperators, partners, permittees, lessees, grantees, and volunteers are aware of any applicable obligations (as specified in agreements, contracts, statements of work, memorandum of understanding, etc.) that they are to uphold, as applicable to the nature and scope of their work.

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(7) Monitor and report compliance with this DR to the DSIO, including activities undertaken to implement the DR.

(8) Ensure that the DSIO is notified of all allegations of compromised scientific integrity referred for an inquiry or investigation, and that the DSIO receives periodic reports on the status of the responses to said allegations.

(9) Ensure that inquiry and investigation reports, decision memoranda, and other substantive documents generated in the course of responding to allegations of compromised scientific integrity are provided to the DSIO, if requested.

(10) Appoint an agency employee to serve as the ASIO. The individual appointed to serve as ASIO must be a career appointee (i.e., non-political appointee), and should have previous experience conducting scientific activities and sufficient institutional authority, stature, and credentials to be able to fulfill the required responsibilities.

e. USDA Staff Offices:

(1) Will apply the responsibilities delineated for agencies in Section 7d(1) through (9) to their staff offices and employees, as applicable, and fulfill these responsibilities.

(2) May, but are not required to, appoint an office employee to serve as the Scientific Integrity Officer.

(a) If an individual is appointed to serve as a Scientific Integrity Officer, the individual must be a career appointee (i.e., non-political appointee), and should have previous experience conducting scientific activities and sufficient institutional authority, stature, and credentials to be able to fulfill the required responsibilities. For the purposes of this DR, individuals appointed to serve as Scientific Integrity Officers for Departmental staff offices are considered to be ASIOs.

(b) If a Departmental staff office does not appoint an individual, the DSIO will fulfill the ASIO responsibilities for that office as these responsibilities apply to the receipt and handling of allegations of compromised scientific integrity.

f. ASIOs will:

(1) Keep agency/staff office leadership informed on the status of implementation of this DR.

(2) Receive and process allegations of compromised scientific integrity in accordance with DM 1074-001.

(3) Conduct an initial assessment of allegations and submitted materials received from the DSIO, OIG, or other sources, following established procedures, to determine whether

the allegations pertain to compromised scientific integrity and the appropriate handling of said allegations.

(4) Notify the DSIO of all allegations of compromised scientific integrity referred for an inquiry or investigation, including notifying the DSIO within 10 days of an ASIO's initial assessment determination that an allegation should be referred for an inquiry.

(5) Coordinate with the DSIO and appropriate employee/labor relations staff on responses to all allegations of compromised scientific integrity referred for an inquiry or investigation so as to facilitate the integrity of, and consistency in, the process used across the Department for responding to said allegations;

(6) Provide oversight of proceedings to address allegations of compromised scientific integrity;

(7) Provide records (e.g., inquiry and investigation reports, evidentiary exhibits, and decision memoranda), when requested, and status reports to the DSIO of the disposition of allegations;

(8) Immediately notify OIG and the DSIO if behavior that is or may be criminal in nature is discovered at any point during the agency/staff office response to allegations of compromised scientific integrity; and

(9) Serve as, and fulfill the responsibilities of, the Agency Research Integrity Officer (ARIO) as described in 2 CFR 422, unless an agency specifically designates another individual to serve as the ARIO for handling allegations of research misconduct involving USDA-funded extramural research.

g. Managers and Supervisors, who are covered under the scope of this DR and/or have management or supervisory responsibilities for employees covered under the scope of this DR, will:

(1) Be aware of and uphold the principles contained in this DR, including the USDA Code of Scientific Ethics (Appendix A);

(2) Implement and comply with this DR and DM 1074-001 as it pertains to their area of management or supervision;

(3) Abide by the USDA Code of Scientific Ethics, and adhere to accepted professional values and practices of the relevant research/scientific communities so as to ensure scientific integrity;

(4) Report to the ASIO any knowledge of compromised scientific integrity;

(5) Ensure that their employees, who are covered by the scope of this DR (*see* Section 3a(2)), are informed about and receive training on this DR; and

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(6) Consult, as appropriate depending upon the nature of the allegation, with the ASIO, human resources officer, contracting and grant personnel, ethics officer, DSIO, OIG, OGC, and the Office of Civil Rights.

h. Employees who are covered by the scope of this DR (*see* Section 3(a)(2)):

(1) Should be aware of the principles contained in this DR, including the USDA Code of Scientific Ethics (Appendix A);

(2) Must comply with this DR and any additional agency/office-specific policies and guidance pertaining to scientific integrity;

(3) Must abide by the USDA Code of Scientific Ethics, and adhere to accepted professional values and practices of the relevant research/scientific communities so as to ensure scientific integrity; and

(4) Are encouraged to report to the ASIO or DSIO any knowledge of compromised scientific integrity.

i. Contractors, cooperators, partners, permittees, lessees, grantees, and volunteers, who engage or assist in the activities identified in Section 3a(2) on behalf of USDA, are expected to uphold the principles of scientific integrity set forth in this DR. However, any express requirements will be set forth in individual agreements, contracts, statements of work, memoranda of understanding, etc., and/or established via issuance of a separate rule or other Departmental policy. ***NOTE:*** *Research institutions that receive allegations of research misconduct involving USDA-funded extramural research should also refer to 2 CFR 422 ("Research Institutions Conducting USDA-Funded Extramural Research; Research Misconduct").*

8. PROCEDURES

a. The procedures for responding to allegations of compromised scientific integrity, including research misconduct, are described in DM 1074-001. The DM establishes a multi-phase framework for responding to allegations of compromised scientific integrity, including, as applicable, inquiry, investigation, adjudication, and appeal phases, consistent with the *Federal Policy on Research Misconduct*. The DM also establishes safeguards for those who make allegations of compromised scientific integrity (informants) in good faith and the subjects (respondents) of said allegations.

b. To establish a finding that scientific integrity has been compromised:

(1) There must be a loss or breach of scientific integrity (*see* Section 9dd(1)) in the conducting or reporting of scientific activities, and/or the use or application of the results of scientific activities; <u>and</u>

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(2) There must be a failure to comply with the policies set forth in this DR or a significant departure from accepted practices of the relevant research, scientific, and/or statistical community;[4] and

(3) The allegation must be proven by a preponderance of evidence.

c. Research misconduct is a subset of compromised scientific integrity.

(1) To establish a finding of research misconduct:

(a) The alleged behavior must fall within the definition of research misconduct (i.e., fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results); and

(b) There must be a significant departure from accepted practices of the relevant research community; and

(c) The misconduct must be committed intentionally, knowingly, or recklessly; and

(d) The allegation must be proven by a preponderance of evidence.

(2) Research misconduct does not include honest error or differences of opinion.

9. DEFINITIONS

a. Adjudication. The stage in response to an allegation of compromised scientific integrity when the outcome of the investigation is reviewed and a determination is made as to whether scientific integrity was compromised and what corrective actions are warranted.

b. Advisory Committee. Any committee, board, commission, council, conference, panel, task force, or other similar group that is established by statute, or established or utilized by the President or by an agency official, for the purpose of obtaining advice or recommendations for the President or on issues or policies within the scope of an agency official's responsibilities.

c. Agency. An organizational unit of the Department, other than a staff office, whose head reports to an Under Secretary.

d. Agency Scientific Integrity Officer (ASIO). The individual appointed by a USDA agency or staff office who is responsible for overseeing agency/staff office responsibilities and activities related to scientific integrity, including receiving and overseeing agency/staff office responses to allegations of compromised scientific

[4] For the purposes of this DR, accepted practices of the relevant research/scientific community include, but are not limited to, those delineated in the USDA Code of Scientific Ethics referenced in DR 1074-001.

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integrity. ***NOTE:*** *For allegations of research misconduct involving USDA-funded extramural research, ASIOs will also serve as, and fulfill the responsibilities of, the ARIO, as described in 2 CFR 422, unless an agency specifically designates another individual to serve as the ARIO.*

e. Allegation. A disclosure of a suspected compromise of scientific integrity through any means of communication. The disclosure may be by written or oral statement, or by other means of communication to a USDA official.

f. Appeal. The stage in the response to an allegation of compromised scientific integrity when a respondent (i.e., the individual against whom the allegation has been made), who has been found to have compromised scientific integrity, may appeal the finding and/or corrective actions to restore scientific integrity.

g. Conflict of Interest. Any financial or non-financial interest that conflicts with the actions or judgments of an individual when conducting scientific activities because it could: (1) impair the individual's objectivity; (2) create an unfair competitive advantage for any person or organization; or (3) create the appearance of either (1) or (2).

h. Corrective Action. A corrective action is an administrative action that is recommended and implemented for the purpose of ensuring and/or restoring scientific integrity based on finding(s) that scientific integrity was compromised. For the purposes of this DR, corrective actions do not include adverse personnel actions or disciplinary actions. ***NOTE:*** *Procedures for implementing adverse personnel actions or disciplinary actions are not covered by this DR or DM 1074-001. Such actions may be proposed and implemented as allowed by and in accordance with other USDA policies and procedures separate from this DR, based on final findings that scientific integrity was compromised (i.e., those findings adjudicated by an agency/staff office and, if appealed, upheld by the USDA Chief Scientist).*

(1) The following is a non-exhaustive list of corrective actions, some or all of which may be recommended and implemented, based on findings that scientific integrity was compromised. The implementation of certain of these actions may require further proceedings as specified in other USDA rules, regulations, or policies.

(a) Government-wide debarment;

(b) Removal from a particular research project, or suspension or termination of an active research award;

(c) Correction or retraction of published scientific products;

(d) Correction or retraction of USDA media releases pertaining to scientific products;

(e) Release of inappropriately suppressed scientific products;

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(f) Monitoring or supervision of future USDA scientific activities, use of scientific information, or dissemination of scientific information;

(g) Required validation of data and/or sources (references and contributors); and/or

(h) Training and/or mentoring.

i. Decision-makers. Employees who may: (1) develop policies or make determinations about policy or management; (2) make determinations about expenditures of USDA funds; (3) implement or manage activities that involve, or rely on, scientific activities; or (4) supervise employees who engage in or report on scientific activities.

j. Designated Federal Officer. An individual designated by the agency head, for each advisory committee for which the agency head is responsible, to implement the provisions of sections 10(e) and (f) of the Federal Advisory Committee Act and any advisory committee procedures of the agency.

k. Extramural Research. Research conducted by any research institution other than the Federal agency to which the funds supporting the research were appropriated. Research institutions conducting extramural research may include Federal research facilities.

l. Fabrication. Making up data or results and recording or reporting them.

m. Falsification. Manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.

n. Financial Interest. Any matter affecting a personal financial interest or a financial interest imputed to the individual (including, but not limited to, the individual's spouse and any entity for which the individual serves in a personal capacity as an officer or board member, such as due to fiduciary duties to the organization under state law).[5]

o. Inappropriate Influence. The attempt to shape the production of a scientific product against the judgment of a non-partisan and apolitical scientific or statistical agency. More specifically, it includes, but is not limited to:

(1) The suppression of an agency's responsibility to offer its best judgment on how to most accurately and reliably study or measure a given phenomenon;

(2) The decision to prevent an agency from using state-of-the-art science;

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[5] *See* 18 U.S.C. 208. This definition will be applied consistently with any rule issued by the U.S. Office of Government Ethics permitting the appointment of Federal employees to serve in their official capacities on the boards of directors and as officers of nonprofit organizations, including scientific organizations, professional societies, and similar bodies that are actively involved in matters under the jurisdiction of the Department. *See* 76 FR 24816 (May 3, 2011).

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(3) The insistence on the preclearance of a scientific product, which is based on state-of-the-art science, for purposes other than providing advance notification or an opportunity to review for technical merit; and/or

(4) The suppression, alteration, or delay of the release of a scientific product for any reason other than technical merit or providing advance notification, as determined through standard agency/staff office procedures.

p. Inquiry. The stage in the response to an allegation of compromised scientific integrity when an assessment is made to determine whether the allegation has substance and whether an investigation is warranted.

q. Intramural Research. Research conducted by a Federal agency to which funds were appropriated for the purpose of conducting the research.

r. Investigation. The stage in the response to an allegation of compromised scientific integrity when the factual record is formally developed and examined, leading to a recommendation to dismiss the allegation, make a finding that scientific integrity was compromised, and/or implement corrective actions to restore scientific integrity.

s. Non-financial Conflict of Interest. Individual participation in a matter where one of the parties has, or is represented by someone with whom the individual has, a covered relationship (including, but not limited to, a spouse's employer and any entity for which the individual is actively involved in a personal capacity).[6]

t. Office of the Secretary. The immediate office of the Secretary, the Deputy Secretary, and the Under and Assistant Secretaries.

u. Plagiarism. The appropriation of another person's ideas, processes, results, or words without giving appropriate credit. ***NOTE:*** *The proposing and conducting of research often involves collaboration and may result in the joint development of products (e.g., concepts, methods, descriptive language, results, etc.). The ownership of such jointly developed products is often unclear, and a collaborative history may support a presumption of implied consent for individual collaborators to independently use jointly developed products. For these reasons, disputes among collaborators pertaining to subsequent independent use of products resulting from prior joint efforts may be determined to involve authorship or credit disputes rather than plagiarism.*

v. Political Interference. The attempt to gain partisan or regional advantage by shaping the production of a scientific product against the judgment of a non-partisan and apolitical statistical or scientific agency. More specifically, it includes, but is not limited to:

(1) The politically motivated suppression of an agency's responsibility to offer its best judgment on how to most accurately and reliably measure a given phenomenon;

[6] *See* 5 C.F.R. 2635.502(b).

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(2) The politically motivated decision to prevent an agency from using state-of-the-art science;

(3) The politically motivated insistence on the pre-clearance of a major scientific product that is based on state-of-the-art science; and/or

(4) The politically motivated suppression, alteration, or delay of the release of a scientific product for any reason other than technical merit or providing advance notification, as determined through standard agency/staff office procedures.

w. Preponderance of the Evidence. Proof by information that, compared with that opposing it, leads to the conclusion that a particular matter or asserted fact is probably more true than not. ***NOTE:*** *A "preponderance of the evidence" is a lower burden of proof than "by clear and convincing evidence" or "beyond a reasonable doubt."*

x. Recklessly. Compromising scientific integrity "recklessly" is characterized by a conscious or willful disregard for ensuring scientific integrity that a reasonable individual would take in like circumstances.

y. Research. Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Research includes all basic, applied, and demonstration research in all fields of science, technology, engineering, and mathematics. This includes, but is not limited to, research in economics, education, linguistics, medicine, nutrition, psychology, natural sciences, social sciences, statistics, and research involving human subjects, animals, and *in vitro* and *in silico* techniques.

z. Research Misconduct. Fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Research misconduct does not include honest error or differences of opinion.

aa. Research Record. The record of data or results that embody the facts resulting from scientific inquiry, and includes, but is not limited to, research proposals, laboratory records, progress reports, abstracts, theses, oral presentations, internal reports, and journal articles. Research records may exist in physical, electronic, or other forms.

bb. Scientific Activities. Activities, such as data collection, inventorying, monitoring, statistical analysis, surveying, observations, experimentation, study, research, analysis, integration, economic analysis, forecasting, predictive analytics, modeling, scientific assessment, and technology development, that involve the application of well-accepted scientific methodologies in a systematic manner.

cc. Scientific Assessment. Evaluation of a body of scientific, economic, or technical knowledge, which typically synthesizes multiple factual inputs, data, models, assumptions, and/or applies best professional judgment to bridge uncertainties in the

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available information. Scientific assessments include, but are not limited to, state-of-science reports; technology assessments; weight-of-evidence analyses; meta-analyses; health, safety, or ecological risk assessments; toxicological characterizations of substances; integrated assessment models; hazard determinations; and exposure assessments.

dd. Scientific Integrity. The condition resulting from adherence to professional values and practices when conducting, reporting, and applying the results of scientific activities that ensures objectivity, clarity, and reproducibility, and that provides insulation from bias, fabrication, falsification, plagiarism, inappropriate influence, political interference, censorship, and inadequate procedural and information security.

(1) Compromise of Scientific Integrity. The loss or breach of scientific integrity in the conducting or reporting of scientific activities, and/or the use or application of the results of scientific activities. Compromised scientific integrity includes, but is not limited to:

(a) Using scientific products that are not representative of the current state of scientific knowledge and research (for example because of a lack of appropriate peer review, poor methodology, or flawed analyses) to inform decision making and policy formulation;

(b) Misrepresenting the underlying assumptions, uncertainties, or probabilities of scientific products;

(c) Inappropriately influencing, or politically interfering with, scientific activities and/or resulting scientific products (*see* Section 9o and v);

(d) Inappropriately influencing, or politically interfering with, the release of scientific products (*see* Section 9o and v);

(e) Inappropriately suppressing or censoring the objective communication of findings (i.e., data and results) resulting from scientific activities; and/or

(f) Inappropriately altering or misrepresenting scientific products in public communications.

(2) Compromised scientific integrity also includes research misconduct (*see* Section 9z).

(3) For the purposes of this DR, compromised scientific integrity does not include ethical improprieties and regulatory non-compliance that do not constitute a loss or breach of scientific integrity as defined in Section 9dd(1). Examples of such improprieties include but are not limited to: misallocation of funds, sexual harassment, discrimination, and breaches of human subject protections or animal welfare requirements. ***NOTE:*** *Breaches of human subject protections or animal welfare requirements should be reported, respectively, to the appropriate*

Institutional Review Board (IRB) or Institutional Animal Care and Use Committee (IACUC).

ee. Scientific Product. The results of scientific activities, including the analysis, synthesis, compilation, or translation of scientific, statistical, economic, and technological information and data into formats for the use of USDA or the Nation. Official policy, budget, or management documents are not considered scientific products. For the purposes of this DR, a regulatory impact analysis is also not considered to be a scientific product; however, the use and representation of scientific information in a regulatory impact analysis is covered by this DR (*see* Section 6c).

ff. Staff Office. A Departmental administrative office whose head reports to an official within the Office of the Secretary.

gg. Statistical Agency. A Federal statistical agency is a unit of the Federal Government whose principal function is the compilation and analysis of data and the dissemination of information for statistical purposes.

hh. Transparent (Transparency). Characterized by visibility or accessibility of information (the quality or state of being transparent).

ii. USDA Departmental Scientific Integrity Officer (DSIO). The individual designated by the USDA Chief Scientist who is responsible for implementing this DR under the direction of the Chief Scientist and the USDA Science Council, and who is responsible for providing oversight of, and consultation on, Departmental and agency responses to allegations of compromised scientific integrity. ***NOTE:*** *For allegations of research misconduct involving USDA-funded extramural research, the DSIO will also serve as, and fulfill the responsibilities of, the USDA RIO, as described in 2 CFR 422.*

jj. USDA Science Council. A group representing USDA mission areas and offices, chaired by the USDA Chief Scientist, to facilitate cross-Department coordination and collaboration among all USDA agencies.

10. ABBREVIATIONS

a. ARIO: Agency Research Integrity Officer
b. ASIO: Agency Scientific Integrity Officer
c. CFR: Code of Federal Regulations
d. DM: Departmental Manual
e. DR: Departmental Regulation
f. FAC: Federal Advisory Committee
g. FR: Federal Register
h. OC: The Office of Communications of the United States Department of Agriculture
i. OE: The Office of Ethics of the United States Department of Agriculture
j. OGC: The Office of the General Counsel of the United States Department of Agriculture

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k. OIG: The Office of Inspector General of the United States Department of Agriculture
l. OMB: The Office of Management and Budget of the Executive Office of the President
m. OSTP: The Office of Science and Technology Policy of the Executive Office of the President
n. PL: Public Law
o. REE: The Research, Education and Economics Mission Area of the United States Department of Agriculture
p. U.S.C.: United States Code
q. USDA: The United States Department of Agriculture
r. USDA DSIO: Departmental Scientific Integrity Officer of the United States Department of Agriculture
s. USDA RIO: The Research Integrity Officer of the United States Department of Agriculture
t. WPA: The Whistleblower Protection Act of 1989
u. WPEA: The Whistleblower Protection Enhancement Act of 2012

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APPENDIX A
USDA CODE OF SCIENTIFIC ETHICS[7]

- I dedicate myself to the pursuit, promotion, and advancement of scientific knowledge.
- I will design, conduct, manage, evaluate, and report scientific research honestly and thoroughly, and will disclose any conflicts of interest to my supervisor or other appropriate USDA official(s) for their determination as to whether a recusal, disclaimer, or other appropriate notification would be appropriate.
- I will prevent abuse of all research resources entrusted to me, and will conduct research involving the participation of human subjects and the use of non-human animals in accordance with applicable, established, ethical standards.
- I will not compromise scientific integrity.
- I will make all reasonable efforts to ensure the accuracy of the research record and to correct identified inaccuracies that pertain to my contribution to the research reported in the research record.
- I will not willfully hinder the research of others.
- I will welcome constructive criticism of my scientific research and offer the same to my colleagues in a manner that fosters mutual respect amid objective scientific debate.
- I will recognize, as appropriate,[8] past and present contributors to my research and will neither accept nor assume unauthorized and/or unwarranted credit for another's accomplishments.
- I will claim authorship for a research product only if I am willing to be held responsible for both the interpretation of the data and the conclusions as presented.
- I will claim authorship for a research product only if I have made a major intellectual contribution (as part of conception, design, data collection, data analysis, or interpretation) and made significant contributions to its preparation (written, reviewed, or edited).
- I will not publish or use the original ideas, unpublished research data, or unpublished findings of others without, as appropriate,[9] securing written approval or providing acknowledgment.
- I will refrain from duplicative publication of the same research findings as original.
- I will show appropriate diligence toward preserving and maintaining research resources, such as records of data and results that are entrusted to me.

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[7] This code of ethics is a modification of the USDA Forest Service Research and Development Code of Scientific Ethics (http://www.fs.fed.us/research/pdf/fs_code_of%20_scientific_ethics.pdf).

[8] *i.e.*, in accordance with accepted practices of the relevant research community.

[9] *i.e.*, in accordance with accepted practices of the relevant research community.

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