

Legal and Administrative Aspects

When faced with planning for either an emergency or a new program initiative, often the programmatic issues or obstacles that need to be addressed take precedence over the related legal and administrative issues. However, as most federal program managers are acutely aware, these legal administrative issues can often prove to be as important as some of the biological/technical issues. For example, will the new program or emergency require the Agency to amend its regulations or issue new regulations? Does the Agency have adequate authority to initiate actions to address the issue? Do the federal rules allow program managers to hire temporary or contract employees?

Many of these issues are addressed in the following section. The first portion will provide a listing of legal authorities under which APHIS carries out its programs. It also includes a list of laws and executive orders that govern Federal rulemaking. This legal section is intended to be only an inventory of regulations, rules, and executive orders that have an impact on APHIS' mission. It is not exhaustive. It is intended to serve only as a reference sheet to program managers. It should also be noted that the legal authorities for conducting APHIS business are complex and multi-faceted, so as new APHIS programs are developed or existing programs are expanded, sometimes legal authorities must be interpreted by legal experts to determine what the Agency's appropriate role is. In these cases, program managers should consult with the Office of the General Counsel (OGC). Each Agency Program Unit should have an appointed contact that can make inquiries with OGC on specific legal questions. Please check with your program's Deputy Administrator's Office for the appropriate contact.

The second portion will provide a brief description of the administrative issues that need to be addressed in the planning process. MRPBS is responsible for providing administrative support to the APHIS Programs in the areas of finance, procurement, personnel, information technology, investigative and enforcement services, property, safety, and security. This Planning Guide provides only a brief outline of the services provided by MRPBS and is in no way all inclusive. For more information, please see the [MRPBS Emergency Response Manual] located at <http://inside.aphis.usda.gov>. The Manual is updated regularly and should be used as a resource when more detailed information is needed.

Overview: Primary Authorities for APHIS Program Work

Animal Care Authorities

- 7 U.S.C. 2131-2159 – Animal Welfare Act. The AWA provides for the humane care and treatment of most warmblooded animals intended for use in research facilities or for exhibition purposes (including at zoos, circuses, and marine mammal facilities) or for use as pets; assures the humane treatment of animals during transportation in commerce; and protects against pet theft by prohibiting the sale or use of animals which have been stolen. The AWA also prohibits staged dogfights, cockfights, bear and raccoon baiting, and similar animal fighting ventures.
- 15 U.S.C. 1821-1831 — Horse Protection Act. The HPA prohibits horses subjected to a process called soring from participating in exhibitions, sales, shows, or auctions. In addition, the Act prohibits drivers from hauling sored horses across State lines to compete in shows.

Wildlife Services Authorities

- 7 U.S.C. 426-426b-426c — The Act of March 2, 1931, and Rural Development, Agriculture, and Related Agencies Appropriations Act of 1988. Wildlife Services is directed by Congress to manage damage and conflicts caused by wildlife and to take any action the Secretary of Agriculture deems necessary in conducting this program.

Plant Protection and Quarantine Authorities

- 7 U.S.C. 7701 et seq. – Plant Protection Act. The Plant Protection Act of 2000 gives APHIS the ability to prohibit or restrict the importation, entry, exportation, and interstate movement of plants, plant products, biological control organisms, noxious weeds, plant pests, or other articles if the prohibition or restriction is necessary to prevent a plant pest or noxious weed from being introduced into or disseminated within the United States. Under the PPA, violators face harsher civil penalties than ever before for smuggling illegal plants or produce that could harbor plant pests or diseases. The PPA gives the Secretary of Agriculture the authority to subpoena documentary evidence and witnesses to prosecute violators. The Act also provides APHIS with a cost recovery mechanism for expenses related to the disposal of abandoned shipments at U.S. ports of entry.
- The Public Health Security and Bioterrorism Response Act of 2002 (P.L. 107-188) — Title II, Sections 211-231, provides for the regulation of certain biological agents and toxins by the Department of Health and Human Services and the Department of Agriculture. The Act requires that entities, such as private, State, and Federal research laboratories, universities, and vaccine companies, that possess, use, or transfer biological agents or toxins deemed a threat to public health and safety or to animal or plant health or products register these agents with the appropriate Federal Department. The Act requires interagency coordination regarding biological agents and toxins that present a threat to both public health and safety and animal health.

Veterinary Services Authorities

- 7 U.S.C. 8301 et seq. – Animal Health Protection Act
The AHPA authorizes APHIS to prohibit or restrict the importation, entry, exportation, and interstate movement of any animal, means of conveyance, or other article if the prohibition or restriction is necessary to prevent a disease or pest of livestock from being introduced into, or disseminated within or from, the United States. The AHPA authorizes additional actions in extraordinary emergencies. It also provides for inspections, seizures, quarantines, and disposal, as well as measures to detect, control, and eradicate diseases and pests of livestock, and for a veterinary accreditation program.
- The AHPA also contains provisions for compensation, civil penalties, and subpoenas.
- The Public Health Security and Bioterrorism Response Act of 2002 (P.L. 107-188) (See previous citation under PPQ authorities).

Other Laws and Executive Orders that Regularly Impact APHIS

Some of the following laws and executive orders apply to rulemaking specifically. Others apply to agency actions generally, whether or not rulemaking is involved. Where possible, this appendix provides guidance concerning applicability.

Federal Register Act (44 U.S.C. 1502 et seq.)

- Requires certain documents, including documents having general applicability and legal effect (e.g., regulations) to be published in the Federal Register.

National Environmental Policy Act (NEPA) (42 U.S.C. 4321 et seq.)

- Requires agencies to evaluate the potential environmental consequences of proposed actions, including, but not limited to, proposed rule, in a forum open to the public. The evaluation may be in the form of either an environmental assessment and finding of no significant impact or, if such a finding cannot be made, an environmental impact statement.

Section 7 of the Endangered Species Act (16 U.S.C. 1536)

- Requires agencies to consult with the Fish and Wildlife Service of the Department of Interior before taking any action, including, but not limited to, rulemaking actions, which could threaten any endangered species of animal or plant.

Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136 et seq.)

- Requires the registration and reregistration of all chemicals intended as pesticides. APHIS must meet FIFRA requirements or EPA can bring an enforcement action against the Agency.

Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations & Low Income Populations

Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks

Executive Order 13112: Invasive Species

Executive Order 13186: Responsibilities of Federal Agencies to Protect Migratory Birds

Executive Order 13141: Environmental Review of Trade Agreements

Executive Order 13101: Greening the Government through Waste Prevention, Recycling, and Federal Acquisition

Executive Order 12843: Procurement Requirements and Policies for Federal Agencies for Ozone-Depleting Substances

Executive Order 12114: Environmental Effects Abroad of Major Federal Actions

Executive Order 12088: Federal Compliance with Pollution Control Standards

Executive Order 11990: Protection of Wetlands

Contact: PPD's Environmental Services (ES) Staff

Executive Order 13175: Consultation & Coordination with Indian Tribal Governments

- Requires agencies to consult with Indian tribal governments about any new regulations that may have substantial direct effects on them and their members.

Contact: APHIS' Native American Working Group

Administrative Procedure Act: (5 U.S.C. 551 et seq.)

- Sets the basic requirements for rulemaking including publishing either the terms or substance of a proposed rule in the Federal Register; the opportunity for public participation through submission of written comments; publishing a final rule in the Federal Register; and providing an effective date for the final rule that is at least 30 days after publication in the Federal Register (unless the rule relieves restrictions, grants an exemption, or there is other good cause for making an exception).
- Any requirement that APHIS wishes to impose on the public on a recurring basis must be imposed through rulemaking in order to be enforceable.

Federal Advisory Committee Act (5 U.S.C App.1)

- Prohibits Federal officials from seeking advice or recommendations from a group that includes anyone other than State, Federal, local and/or tribal government officials, unless the group has been chartered as an advisory committee under this Act. NOTE: Agencies may seek advice and recommendations from the public at large, including industry groups, through an advance notice of proposed rulemaking or other request for information published in the Federal Register.

Congressional Review Act of 1996 (5 U.S.C. 801 et seq.)

- Requires agencies to submit all interim and final rules to Congress before the scheduled effective dates of the rules.
- Requires a waiting period of 60 days after publication before a “major” (“economically significant”) rule may take effect, except in an emergency situation.

Negotiated Rulemaking Act (5 U.S.C. 561 et seq.)

- Sets out procedures for conducting negotiated rulemaking, consistent with the Administrative Procedures Act. Among other things, requires any group convened for negotiated rulemaking to be established in accordance with the Federal Advisory Committee Act.

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1501 et seq.)

- Requires Federal Agencies to prepare a written statement, including a cost-benefit analysis, for any proposed or final rule likely to result in State, local, or tribal government or private sector expenditures of \$100 million or more in any one year.

Executive Order 12372: Intergovernmental Review of Federal Programs - Concerns with State and local governments who would be directly affected by proposed Federal financial assistance or direct Federal development.

Executive Order 12612: Federalism – Requires agencies to examine the need and authority for any Federal action that would limit the policy making discretion of the States.

Executive Order 12630: Government Actions and Interference with Constitutionally Protected Property – Requires agencies to evaluate regulations that having takings implications on private property. A “Takings Impact

Assessment” may be required.

Executive Order 12988: Civil Justice Reform – Requires agencies to draft regulations clearly and in ways that minimize litigation; requires agencies to specify any preemptive or retroactive effect of regulations, and to specify in the regulations whether any administrative proceedings are required before parties may file suit in court challenging the regulations.

Executive Order 12606: The Family – Requires agencies to consider the potential negative effects of proposed rules on the formation, maintenance, and well-being of the family.

Contact: PPD’s RAD Staff

The Federal Crop Insurance Reform and Department of Agriculture Reorganization Act of 1994 (7 U.S.C. 2204e)

- Requires that USDA prepare risk and cost-benefit analyses for any major rule (those designated “economically significant” by OMB). The analyses must describe the nature of the risk, the need for reducing it, alternatives for reducing it, and the costs and benefits of the alternatives.

Contact: PPD’s RAD, Policy Analysis & Development (PAD), or Risk Analysis Systems (RAS) Staff

Executive Order 12866: Regulatory Planning & Review—
September 1993

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September 1993

- Requires agencies to notify OMB of ALL intended regulatory actions.
- Provides for OMB review of actions deemed “significant” or “economically significant.”
- Requires agencies to assess costs and benefits of rules designated “significant” or “economically significant” and to issue rules only when

benefits exceed costs.

Contact: PPD’s RAD or PAD Staff

Regulatory Flexibility Act (5 U.S.C. 601 et seq.)

- Requires agencies to examine the potential economic effects of rules on small U.S. businesses, non-profit organizations, and small governmental jurisdictions. This analysis is required for almost all regulations.

Contact: PPD’s PAD Staff

Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 et seq.)

- Provides new avenues for small businesses to participate in and have access to the federal regulatory arena. For example, it permits judicial review of agencies’ compliance with the Regulatory Flexibility Act. It also requires agencies to publish compliance guides in plain language explaining how small firms can comply with regulations that have a significant small business impact; establish a system for addressing compliance inquiries from small business; and establish a policy to provide for the reduction, and under appropriate circumstances, for the waiver of civil penalties for violations of statutory or regulatory requirements by a small business.

Contact: PPD’s PAD Staff or MRPBS’ Investigative and Enforcement Staff

Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq)

- Requires agencies to obtain approval from OMB before collecting information from the public or requiring them to keep records.
- Prohibits the collection of information, even on a voluntary basis, from 10 or more persons, unless the information collection has been approved by OMB.

- The Act applies not only to information collections and recordkeeping required by regulations, but also to nonrulemaking activities, such as surveys.

Contact: MRPBS/Information Technology AIM Branch

Government Paperwork Elimination Act (Pub. L. 107-277, Title XVII)

- Specifies that electronic records and related electronic signatures can not be denied legal effect, validity, or enforceability; and requires agencies provide for their use and acceptance when practicable.
- Requires agencies to provide the option of electronic maintenance, submission, or disclosure of information, when practicable, as a substitute for paper.

Contact: MRPBS/Information Technology AIM Branch

Rehabilitation Act (Section 508)

- Requires electronic and information technology developed, procured, maintained or used by the Federal government be accessible to people with disabilities.
- Requires that all Federal employees and members of the public who have disabilities have access to and use of information and services that is comparable to the access and use available to non-disabled individuals.

Contact: MRPBS/Information Technology /FPS Branch

Public Law 107-347 (Title III)

- Requires agency-wide information security program to protect all information systems that support the operations and assets of the agency including those provided or managed by another agency, contractor, or other source.

Clinger-Cohen Act of 1996 (40 U.S.C. 1401 (3))

- Requires the management of all information technology systems using performance and or results – based management practices.

Contact: MRPBS/Information Technology /AIM Branch

The Privacy Act (5 U.S.C. 552 a)

- Establishes certain controls over what personal information is collected by the Federal Government and how it is used. It applies only to records about individuals maintained in a “system of records” and permits an individual to gain access to most personal information and to request amendments to those records.

Contact: Legislative & Public Affairs –Freedom of Information (FOIA) Staff

The Freedom of Information Act (5 U.S.C. 552)

- Tells how the public may request Agency records and requires Federal agencies to make their records promptly available to any person who makes a proper request.

Contact: Legislative & Public Affairs –Freedom of Information (FOIA) Staff

Title VI Civil Rights Act of 1964 (42 USC 2000d et.seq.)

Title IX Education Amendments of 1972 (20 USC 1681)

Section 504 Rehabilitation Act 1973 (29 USC 794)

Age Discrimination Act 1975 (42 USC 6101)

- Prohibits discrimination in programs and activities receiving Federal financial assistance from APHIS. Prohibited bases of discrimination are race, color, national origin, disability, sex (educational programs and activities only), and age.

Title 7, Code of Federal Regulations, Part 15d

- Prohibits discrimination in programs and activities conducted by APHIS. Prohibited bases of discrimination are race, color, religion, sex, age, national origin, marital status, familial status, sexual orientation, or disability, or because all or part of an individual's income is derived from any public assistance program.

Title VII Civil Rights Act of 1964(42 USC 2000e, et. seq.)

Rehabilitation Act of 1973 (29 USC 791)

Age Discrimination in Employment Act (29 USC 621)

Title 29, Code of Federal Regulations, Part 1614, Federal Sector EEO

- Prohibits discrimination in employment and application for employment. Prohibited bases of discrimination are race, color, religion, sex, national origin, disability, and age. Title 29 CFR Part 1614 details federal sector processing of complaints.

Contact: APHIS Civil Rights Enforcement and Compliance:
202-720-6312

Regulatory Work Plan Checklist

Before submitting a regulatory work plan, consider the following questions. If you cannot answer “yes” to any of them, you may not be ready to submit the work plan.

- _____ Does APHIS have the statutory authority to take this action?
- _____ Do you know what is allowed or required under the current Code of Federal Regulations (CFR)?
- _____ Are you sure that the current regulations must be changed in order for this action to be taken? Have you identified the exact regulations that must be changed?
- _____ If the action affects trade, do you know if there is an international standard accepted by OIE, IPPC, or NAPPO related to this action? If you do not choose to use an internationally accepted standard, are you prepared to explain why? You may wish to consult with your program’s trade policy advisor or the Trade Support Team, International Services.
- _____ Is there a sound scientific basis for the action you wish to take? If a risk assessment is necessary, has one been completed? You may wish to consult with PPD-RAS.
- _____ If this action is based on any research, survey, or study, has the research, survey, or study been completed, and do you possess documentation of the results? If this action is based on any other documentation, do you have the documentation?
- _____ Do you really want to take this action? Have you thoughtfully considered the consequences, including any potential environmental effects, burdens on regulated parties (particularly small businesses), opposition by special interest groups, or implications for international trade?
- _____ If this action imposes any restriction or other requirement, is the action enforceable? Is APHIS prepared to enforce it? You may want to consult with Investigative and Enforcement Services.
- _____ Have you considered whether this action will require an environmental assessment under NEPA? You may want to contact PPD-ES.
- _____ Have you consulted with other offices in APHIS which may have an interest in this action, or be affected by this action? (Consider field offices as well as headquarters staff.)
- _____ Have you considered whether and how the action could affect inspectors and/or the inspection procedures at Customs and Border Protection, DHS?
- _____ Have you considered whether other agencies within or outside the Department of Agriculture should be consulted or involved in developing this regulation?
- _____ If you are considering making any related changes to the regulations now or in the near future, have you thought about requesting these in the same work plan? (This may or may not be appropriate. Contact RAD to discuss specific actions.)

_____ Have any issues that might impede progress in drafting the regulation been resolved? Is a program contact ready to work with RAD to develop the regulation?

_____ Have you considered alternatives? A description of alternatives considered, as well as an analysis of their costs and benefits, may be required for the rulemaking. You may wish to consult with PPD-PAD.

APHIS Regulatory Workplan

(Revised April 2004)

Short title for this action:

Please sign and date. Then send to the next office.

1. Originating Office: _____

2. Regulatory Liaison for Program: _____

Is this action related to the functions transferred from APHIS to the DHS? ___ yes ___ no

3. Deputy Administrator: _____

Deputy Administrator's Recommended Designation of Significance:

_____ NOT SIGNIFICANT

_____ SIGNIFICANT

_____ ECONOMICALLY SIGNIFICANT

4. Regulatory Analysis and Development
APHIS Docket Number:

5. Assistant Commissioner, Office of Field Operations,
Bureau of Customs and Border Protection, DHS:

Does the Assistant Commissioner wish to review a copy of the draft regulation? ___ yes ___ no

6. Administrator: _____

(Please hold for Judy Lee, Regulatory Analysis and Development Staff)

7. OBPA: _____

OBPA's Recommended Designation of Significance:

_____ NOT SIGNIFICANT

_____ SIGNIFICANT

_____ ECONOMICALLY SIGNIFICANT

8. Under Secretary (signs inside)

9. Julie Hetrick, OBPA
Room 118-E, Whitten Building
Call 720-1272 for pickup

10. Susan Gallagher, PPD-RAD
4700 River Road Unit 118
Riverdale, MD 20737
734-7187

U.S. Department of Agriculture Animal and Plant Health Inspection Service Regulatory Workplan

APHIS Docket No. 1. Under Secretary's Recommended Designation of Significance: _____ NOT SIGNIFICANT _____ SIGNIFICANT _____ ECONOMICALLY SIGNIFICANT Signature: (Under Secy.) Date: _____ Major under Public Law 103-354 (ORACBA)	Workplan requires OMB review: Additional Instructions from Under Secretary (optional): OBPA WORKPLAN # - Date: _____ OMB's Designation: Date: _____ RIN: _____
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2. Descriptive Title: (include CFR citation, e.g., 9 CFR part 93, 7 CFR 319.56, etc.)

Note: For help in completing this workplan, contact the Regulatory Analysis and Development (RAD) Staff, PPD, at (301) 734-8682. Also, see contacts for assistance listed in specific sections.

3. Type of Action:

Notice: _____	Proposal: _____	Advance Notice of Proposed Rulemaking: _____	
Interim: _____	Final: _____	Direct Final: _____	Other: _____

4. Description of Action and Agency Contact:

- a. Briefly describe what the current regulations require or allow, how you wish to change them, what triggered the need for this change, and the expected results of this change.
- b. Briefly discuss other issues associated with this rulemaking, including any significant changes in program operations; effects on other Federal agencies and State and local governments and the extent of any related consultations; alternatives considered; time pressures (state here if docket needs to be published by a specific date and why); and why the regulatory action is important, sensitive, controversial, or precedent setting.
- c. Name, title, telephone number and e-mail address of agency contact:

5. Briefly discuss the potential economic effects of this action, including benefits and costs, economic effects on small entities, and budgetary effects. For information or assistance, contact Policy Analysis and Development, PPD: (301) 734-8667.

6. If this action is based on a consideration of plant or animal pest or disease risk, it may need to be supported by risk documentation (e.g., a risk assessment, risk analysis, and/or risk management document). Please indicate whether such documentation has been prepared, identify it, and state where a copy may be obtained. For information or assistance, contact Risk Analysis Systems, PPD, (301) 734-8017.

7. Agencies must consider the potential environmental effects of a regulatory action, including effects on human health.

a. Is this action based on a consideration of plant or animal pest or disease risk, including means of avoiding or mitigating risk? yes no

If yes, APHIS procedures in 7 CFR part 372 for implementing the National Environmental Policy Act (NEPA) generally require that an environmental assessment (EA) be prepared, although there are exceptions (e.g., pest or disease risks are de minimis).

Please contact Environmental Services, PPD, at (301) 734-8565, for advice on whether an EA should be prepared and assistance with preparation or, alternatively, assistance in documenting why an EA is not necessary.

Please check one of the following:

An EA is being or has been prepared by (name).

A document has been prepared explaining why an EA is not needed. (Please attach document signed by preparer.)

b. Other environmental requirements, including Executive Order 12898, "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations," and Executive Order 13045, "Protection of Children from Environmental Health Risks and Safety Risks," may also apply. For information and assistance, contact Environmental Services, PPD, (301) 734-8565.

Please check one of the following:

I have consulted PPD-ES or other environmental specialist (name) and no other environmental documentation is required.

I have consulted PPD-ES or other environmental specialist (name), and (name) is preparing documentation to address (executive order or other requirement).

8. Will this action affect the importation of articles into the United States or the interstate movement of articles that are also traded internationally?

yes no

If yes, please answer the following questions. For advice or assistance, contact the Trade Support Team, (202) 720-7677.

- a. Is this action consistent with U.S. obligations under the World Trade Organization Agreement on Sanitary and Phytosanitary Measures, including the principles of transparency, equivalency, and regionalization?
- b. Is there an international standard relevant to this action? If so, please cite [OIE, IPPC, NAPPO] [article/provision/ chapter].
- c. Is this action consistent with any international standard cited above? (Leave blank or type N/A if there is no relevant international standard.)
- d. If the answer to question (a) or (c) is no, please explain.
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9. Executive Order 13175, Consultation and Coordination with Indian and Tribal Governments, states that agencies must consult with Indian tribal governments about any new regulations that may have substantial direct effects on them and their members. Will this rule regulate an area that may include tribal lands or regulate articles used by tribes on their lands? For more information, contact Rick Wadleigh, APHIS Native American Program Coordinator, at (202) 720-8127 or (303) 324-9519, or a headquarters representative of the APHIS Native American Working Group (directory at <http://www.aphis.usda.gov/anawg/staterep.html>).
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10. The Paperwork Reduction Act of 1995 requires agencies to obtain approval from the Office of Management and Budget before implementing any new information collection requirements. Will this rule require the submission of information or recordkeeping? If so, please contact Forms, Issuances, and Records Management (FIRM), MRPBS, at (301) 734-7477. FIRM can advise you of whether OMB approval will be required and explain the process for obtaining it.
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11. State briefly what sections of the CFR will need to be changed as a result of this action:(It is not necessary to show how the sections will be amended.)
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12. If this action is related to functions transferred from APHIS to the Department of Homeland Security, describe any new activities DHS will need to undertake to carry out or enforce this change, describe the types of locations where the new activities will occur, and estimate whether the new activities are likely to require significant increases in personnel, equipment, or other expenses. For information or assistance, contact:
- For plants or plant products: Assistant Director for Regulatory Coordination, PPQ, at (301) 734-8790.
 - For live animals, embryos, or semen: Director, Select Agent, Organisms and Vectors, and Animals at (301) 734-3277.
 - For animal products or byproducts: Assistant Director, Veterinary Regulatory Support, PPQ, at (301) 734-7633; or Director, Technical Trade Services Team--Byproducts, VS, at (301) 734-3277.

13. What other APHIS staffs (or units outside APHIS) should be made aware of or involved in this regulatory change? Please list those to which RAD should send a copy of the workplan. Be as specific as possible (e.g., list a specific name/staff rather than PPQ or VS).

Please route a paper copy of this workplan in accordance with the cover sheet. Please send an electronic copy of this workplan to RAD c/o Wanda L Moore/MD/APHIS/USDA.