

Animal and Plant Health Inspection Service, USDA

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necessary auxiliary services after normal working hours or on holidays, when these services come within the scope of the Act of August 28, 1950 (7 U.S.C. 2260).

§ 371.14 Availability of information and records.

Any person desiring information or to comment on the programs and functions of the agency should address correspondence to the appropriate Deputy Administrator or Director, APHIS, U.S. Department of Agriculture, Washington, DC 20250. The availability of information and records of the agency is governed by the rules and regulations in part 370 of this chapter.

PART 372—NATIONAL ENVIRONMENTAL POLICY ACT IMPLEMENTING PROCEDURES

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AUTHORITY: 42 U.S.C. 4321 *et seq.*; 40 CFR 1500–1508; 7 CFR 1b, 2.22, 2.80, and 371.9.

SOURCE: 60 FR 6002, Feb. 1, 1995, unless otherwise noted.

§ 372.1 Purpose.

These procedures implement section 102(2) of the National Environmental Policy Act (NEPA) by assuring early and adequate consideration of environmental factors in Animal and Plant Health Inspection Service planning and decisionmaking and by promoting the effective, efficient integration of all relevant environmental requirements under the NEPA. The goal of timely, relevant environmental analysis will be secured principally by adhering to the NEPA implementing regulations (40 CFR parts 1500–1508), especially provisions pertaining to timing (§ 1502.5),

integration (§ 1502.25), and scope of analysis (§ 1508.25).

[60 FR 6002, Feb. 1, 1995, as amended at 83 FR 24009, May 24, 2018]

§ 372.2 Designation of responsible APHIS official.

The Administrator of APHIS, or an agency official to whom the Administrator may formally delegate the task, is responsible for overall review of APHIS' NEPA compliance.

§ 372.3 Information and assistance.

Information, including the status of studies, and the availability of reference materials, as well as the informal interpretations of APHIS' NEPA procedures and other forms of assistance, will be made available upon request to the APHIS NEPA contact at: Policy and Program Development, APHIS, USDA, Attention: NEPA Contact, 4700 River Road Unit 149, Riverdale, MD 20737–1238, (301) 851–3043.

[83 FR 24010, May 24, 2018]

§ 372.4 Definitions.

The terminology and definitions set forth in the Council on Environmental Quality's (CEQ) implementing regulations at 40 CFR part 1508 are incorporated herein. In addition, the following terms, as used in these procedures, are defined as follows:

APHIS. The Animal and Plant Health Inspection Service (APHIS).

Decisionmaker. The agency official responsible for signing the document based on a categorical exclusion or findings of no significant impact (FONSI) and environmental assessment or the record of decision following the environmental impact statement (EIS) process.

Department. The United States Department of Agriculture (USDA).

Environmental unit. The analytical unit in Policy and Program Development responsible for coordinating APHIS' compliance with NEPA and other environmental laws and regulations.

[60 FR 6002, Feb. 1, 1995, as amended at 83 FR 24010, May 24, 2018]

§ 372.5 Classification of actions.

(a) *Actions normally requiring environmental impact statements.* This class of policymakings and rulemakings seeks to establish programmatic approaches to animal and plant health issues. Actions in this class typically involve the agency, an entire program, or a substantial program component and are characterized by their broad scope (often global or nationwide) and potential effect (impacting a wide range of environmental quality values or indicators, whether or not affected individuals or systems may be completely identified at the time). Ordinarily, new or untried methodologies, strategies, or techniques to deal with pervasive threats to animal and plant health are the subjects of this class of actions. Alternative means of dealing with those threats usually have not been well developed. Actions in this class include:

- (1) Formulation of contingent response strategies to combat future widespread outbreaks of animal and plant diseases; and
- (2) Adoption of strategic or other long-range plans that purport to adopt for future program application a preferred course of action.

(b) *Actions normally requiring environmental assessments but not necessarily environmental impact statements.* This class of APHIS actions may involve the agency as a whole or an entire program, but generally is related to a more discrete program component and is characterized by its limited scope (particular sites, species, or activities) and potential effect (impacting relatively few environmental values or systems). Potential environmental impacts associated with the proposed action are not considered potentially significant at the outset of the planning process. Any effects of the action on environmental resources (such as air, water, soil, plant communities, animal populations, or others) or indicators (such as dissolved oxygen content of water) can be reasonably identified, and mitigation measures are generally available and have been successfully employed. Unless the actions are categorically excluded as provided in paragraph (c) of this section, actions in this class include:

(1) Policymakings and rulemakings that seek to remedy specific animal and plant health risks or that may affect opportunities on the part of the public to influence agency environmental planning and decisionmaking. Examples of this category of actions include:

- (i) Development of program plans that seek to adopt strategies, methods, and techniques as the means of dealing with particular animal and plant health risks that may arise in the future; and
- (ii) Implementation of program plans at the site-specific, action level.

(2) Planning, design, construction, or acquisition of new facilities, or proposals for modifications to existing facilities.

(3) Disposition of waste and other hazardous or toxic materials at laboratories and other APHIS facilities.

(4) Approvals and issuance of permits for proposals involving regulated genetically engineered organisms or products, or regulated nonindigenous species.

(5) Programs or statewide activities to reduce damage or harm by a specific wildlife species or group of species, such as deer or birds, or to reduce a specific type of damage or harm, such as protection of agriculture from wildlife depredation and disease; for the management of rabies in wildlife; or for the protection of threatened or endangered species.

(6) Research or testing that will be conducted outside of a laboratory or other containment area or reaches a stage of development (e.g., formulation of premarketing strategies) that forecasts an irretrievable commitment to the resulting products or technology.

(c) *Categorically excluded actions.* This class of APHIS actions shares many of the same characteristics—particularly in terms of the extent of program involvement, as well as the scope, effect of, and the availability of alternatives to proposed actions—as the class of actions that normally requires environmental assessments but not necessarily environmental impact statements. The major difference is that the means through which adverse environmental impacts may be avoided or minimized have actually been built right into the

actions themselves. The efficacy of this approach generally has been established through testing and/or monitoring. The Department of Agriculture has also promulgated a listing of categorical exclusions that are applicable to all agencies within the department unless their procedures provide otherwise. Those categorical exclusions, codified at 7 CFR 1b.3(a), are entirely appropriate for APHIS. Other actions in this class include:

(1) *Routine measures.* (i) Routine measures, such as identifications, inspections, surveys, sampling that does not cause physical alteration of the environment, testing, seizures, quarantines, removals, sanitizing, inoculations, control, and monitoring employed by agency programs to pursue their missions and functions. Such measures may include the use—according to any label instructions or other lawful requirements and consistent with standard, published program practices and precautions—of chemicals, pesticides, or other potentially hazardous or harmful substances, materials, and target-specific devices or remedies, provided that such use meets all of the following criteria (insofar as they may pertain to a particular action):

(A) The use is localized or contained in areas where humans are not likely to be exposed, and is limited in terms of quantity, i.e., individualized dosages and remedies;

(B) The use will not cause contaminants to enter water bodies, including wetlands;

(C) The use does not adversely affect any federally protected species or critical habitat; and

(D) The use does not cause bioaccumulation.

(ii) Examples of routine measures include:

(A) Inoculation or treatment of discrete herds of livestock or wildlife undertaken in contained areas (such as a barn or corral, a zoo, an exhibition, or an aviary);

(B) Use of vaccinations or inoculations including new vaccines (e.g., genetically engineered vaccines) and applications of existing vaccines to new species provided that the project is conducted in a controlled and limited

manner, and the impacts of the vaccine can be predicted; and

(C) Isolated (for example, along a highway) weed control efforts.

(2) *Research and development activities.*

(i) Activities limited in magnitude, frequency, and scope that occur in laboratories, facilities, pens, or field sites. Examples are:

(A) Vaccination trials that occur on groups of animals in areas designed to limit interaction with similar animals, or include other controls needed to mitigate potential risk.

(B) Laboratory research involving the evaluation and use of chemicals in a manner not specifically listed on the product label pursuant to applicable Federal authorizations.

(C) The development and/or production (including formulation, packaging or repackaging, movement, and distribution) of articles such as program materials, devices, reagents, and biologics that were approved and/or licensed in accordance with existing regulations, or that are for evaluation in confined animal, plant, or insect populations under conditions that prevent exposure to the general population.

(D) Research evaluating wildlife management products or tools, such as animal repellents, frightening devices, or fencing, that is carried out in a manner and area designed to eliminate the potential for harmful environmental effects and in accordance with applicable regulatory requirements.

(ii) Development, production, and release of sterile insects.

(3) *Licensing and permitting.*

(i) Issuance of a license, permit, authorization, or approval to ship or field test previously unlicensed veterinary biologics, including veterinary biologics containing genetically engineered organisms (such as vector-based vaccines and nucleic acid-based vaccines);

(ii) Issuance of a license, permit, authorization, or approval for movement or uses of pure cultures of organisms (relatively free of extraneous microorganisms and extraneous material) that are not strains of quarantine concern and occur, or are likely to occur, in a State's environment; or

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(iii) Permitting for confined field releases of genetically engineered organisms and products; and

(iv) Permitting of:

(A) Importation of nonindigenous species into containment facilities,

(B) Interstate movement of nonindigenous species between containment facilities, or

(C) Releases into a State's environment of pure cultures of organisms that are either native or are established introductions.

(4) [Reserved]

(5) *Minor renovation, improvement, and maintenance of facilities.* Examples are:

(i) Renovation of existing laboratories and other facilities.

(ii) Functional replacement of parts and equipment.

(iii) Minor additions to existing facilities.

(iv) Minor excavations of land and repairs to properties.

(d) *Exceptions for categorically excluded actions.* Whenever the decision-maker determines that a categorically excluded action may have the potential to affect "significantly" the quality of the "human environment," as those terms are defined at 40 CFR 1508.27 and 1508.14, respectively, an environmental assessment or an environmental impact statement will be prepared. For example:

(1) When any routine measure, the incremental impact of which, when added to other past, present, and reasonably foreseeable future actions (regardless of what agency or person undertakes such actions), has the potential for significant environmental impact;

(2) When a previously licensed or approved biologic has been subsequently shown to be unsafe, or will be used at substantially higher dosage levels or for substantially different applications or circumstances than in the use for which the product was previously approved; or

(3) When a confined field release of genetically engineered organisms or products involves new species or organisms or novel modifications that raise new issues.

[60 FR 6002, Feb. 1, 1995; 60 FR 13212, Mar. 10, 1995; 83 FR 24010, May 24, 2018; 85 FR 29838, May 18, 2020]

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§ 372.6 Early planning.

Prospective applicants are encouraged to contact APHIS program officials to determine what types of environmental analyses or documentation, if any, need to be prepared.

[83 FR 24011, May 24, 2018]

§ 372.7 Planning and decision points and public involvement.

(a) *Major planning and decisions points.* The NEPA process will be fully coordinated with APHIS planning in cooperation with program personnel. Specific decision points or milestones will be identified and communicated to the public and others in a notice of intent and in the context of the public scoping process.

(b) *Public involvement.* There will be an early and open process for determining the scope of issues to be addressed in the environmental impact statement process.

(1) A notice of intent to prepare an environmental impact statement will be published in the FEDERAL REGISTER as soon as it is determined that a proposed major Federal action has the potential to affect significantly the quality of the human environment. The notice may include a preliminary scope of environmental study. All public and other involvement in APHIS' environmental impact statement process, including the scoping process, commenting on draft documents, and participation in the preparation of any supplemental documents, will be pursuant to CEQ's implementing regulations.

(2) Opportunities for public involvement in the environmental assessment process will be announced in the same fashion as the availability of environmental assessments and findings of no significant impact.

(3) Notification of the availability of environmental assessments and findings of no significant impact for proposed activities will be published in the FEDERAL REGISTER, unless it is determined that the effects of the action are primarily of regional or local concern. Where the effects of the action are primarily of regional or local concern, notice will normally be provided through

publication in a local or area newspaper of general circulation and/or the procedures implementing Executive Order 12372, "Intergovernmental Review of Federal Programs."

(4) All environmental documents and comments received will be made available to the public via *Regulations.gov*.

[60 FR 6002, Feb. 1, 1995, Redesignated and amended at 83 FR 24011, May 24, 2018]

§ 372.8 Processing and use of environmental documents.

(a) Environmental assessments will be forwarded immediately upon completion to the decisionmaker for a determination of whether the proposed action may have significant effects on the quality of the human environment, and for the execution, as appropriate, of a finding of no significant impact or a notice of intent to prepare an environmental impact statement. This determination is based on information provided in the NEPA document and available in the record.

(1) The availability of environmental assessments will be announced by publishing a notice consistent with the notification provisions of § 372.7.

(2) Comments, if any, will be transmitted, together with any analyses and recommendations, to the APHIS decisionmaker who may then take appropriate action.

(3) Changes to environmental assessments and findings of no significant impact that are prompted by comments, new information, or any other source, will normally be announced in the same manner as the notice of availability prior to implementing the proposed action or any alternative. APHIS will mail notice upon request.

(b) Environmental impact statements will be processed from inception (publication of the notice of intent) to completion (publication of a final environmental impact statement or a supplement) according to the Council on Environmental Quality implementing regulations.

(c) For rulemaking or adjudicatory proceedings, relevant environmental documents, comments, and responses will be a part of the administrative record.

(d) For all APHIS activity that is subject to the NEPA process, relevant

environmental documents, comments, and responses will accompany proposals through the review process.

(e) The APHIS decisionmaker will consider the alternatives discussed in environmental documents in reaching a determination on the merits of proposed actions.

(f) APHIS will implement mitigation and other conditions established in environmental documentation and committed to as part of the decision-making process.

[60 FR 6002, Feb. 1, 1995, Redesignated and amended at 83 FR 24011, May 24, 2018]

§ 372.9 Supplementing environmental impact statements.

Once a decision to supplement an environmental impact statement is made, a notice of intent will be published. The supplemental document will then be processed in the same fashion (exclusive of scoping) as a draft and a final statement (unless alternative procedures are approved by CEQ) and will become part of the record.

[60 FR 6002, Feb. 1, 1995, Redesignated and amended at 83 FR 24011, May 24, 2018]

§ 372.10 Process for rapid response to emergencies.

When it is determined (by the Administrator or the delegated Agency official responsible for environmental review) that an emergency exists that requires immediate action before preparing and completing the usual NEPA review, then the provisions of this section apply.

(a) The Administrator or the delegated Agency official responsible for environmental review may take actions that are necessary to control the immediate impacts of the emergency and that are urgently needed to prevent imminent damage to public health or safety, or prevent threats to valuable resources. When taking such actions, the Administrator or the delegated Agency official responsible for environmental review will consider the probable environmental consequences of the emergency action and mitigate foreseeable adverse environmental effects to the extent practicable.

(b) If a proposed emergency action is normally analyzed in an environmental assessment as described in § 372.5 and

the nature and scope of proposed emergency actions are such that there is insufficient time to prepare an EA and FONSI before commencing the proposed action, the Administrator shall consult with APHIS' Chief of Environmental and Risk Analysis Services about alternative arrangements for NEPA compliance. APHIS' Chief of Environmental and Risk Analysis Services may authorize emergency alternative arrangements for completing the required NEPA compliance documentation. Any alternative arrangements must be documented and notice of their use provided to CEQ.

(c) If a proposed emergency action is likely to result in significant environmental impacts, then APHIS will immediately consult with CEQ and request alternative arrangements in accordance with CEQ regulations at 40 CFR 1506.11. Such alternative arrangements will apply only to the proposed actions necessary to control the immediate impacts of the emergency. Other proposed actions remain subject to NEPA analysis and documentation in accordance with the CEQ regulations and these regulations.

[83 FR 24011, May 24, 2018]

PART 380—RULES OF PRACTICE GOVERNING PROCEEDINGS UNDER CERTAIN ACTS

Subpart A—General

Sec.

380.1 Scope and applicability of rules of practice.

Subpart B—Supplemental Rules of Practice

380.10 Stipulations.

AUTHORITY: 7 U.S.C. 7701–7772 and 7781–7786; 16 U.S.C. 1540(a), 3373(a) and (b); 7 CFR 2.22, 2.80, and 371.3.

Subpart A—General

§ 380.1 Scope and applicability of rules of practice.

(a) The Uniform Rules of Practice for the Department of Agriculture promulgated in subpart H of part 1, subtitle A, title 7 CFR are the Rules of Practice applicable to adjudicatory administra-

tive proceedings under the following statutory provisions:

(1) The Plant Protection Act, section 424 (7 U.S.C. 7734),

(2) Endangered Species Act Amendments of 1973, as amended, section 11(a), 16 U.S.C. 1540(a), and

(3) Lacey Act Amendments of 1981, as amended, section 4(a) and (b), (16 U.S.C. 3373 (a) and (b)).

(b) In addition, the Supplemental Rules of Practice set forth in subpart B of this part are applicable to such proceedings.

[66 FR 21061, Apr. 27, 2001]

Subpart B—Supplemental Rules of Practice

§ 380.10 Stipulations.

(a) At any time prior to the issuance of a complaint seeking a civil penalty under any of the Acts listed in § 380.1, the Administrator, in his discretion, may enter into a stipulation with any person in which:

(1) The Administrator or the Administrator's delegate gives notice of an apparent violation of the applicable Act, or the regulations issued thereunder, by such person and affords such person an opportunity for a hearing regarding the matter as provided by such Act;

(2) Such person expressly waives hearing and agrees to pay a specified penalty within a designated time; and

(3) The Administrator agrees to accept the specified penalty in settlement of the particular matter involved if the penalty is paid within the designated time.

(b) If the specified penalty is not paid within the time designated in such a stipulation, the amount of the stipulated penalty shall not be relevant in any respect to the penalty which may be assessed after issuance of a complaint.

[48 FR 33468, July 22, 1983]

PARTS 381–399 [RESERVED]