Environmental Policy Act implementing regulations (40 CFR parts 1500–1508), especially provisions pertaining to timing (§1502.5), integration (§1502.25), and scope of analysis (§1508.25).

§ 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 Environmental Analysis and Documentation, Biotechnology, Biologics, and Environmental Protection, APHIS, USDA, P.O. Drawer 810, Riverdale MD 20738, (301) 436–8565 (Hyattsville) or (301) 734–8565 (Riverdale).

§ 372.4 Definitions.

The terminology set forth in the Council on Environmental Quality's (CEQ) implementing regulations at 40 CFR part 1508 is 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 executing findings of no significant impact in the environmental assessment process and the record of decision in the environmental impact statement process.

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

Environmental unit. Environmental Analysis and Documentation, the analytical unit in Biotechnology, Biologics, and Environmental Protection responsible for coordinating APHIS' compliance with the National Environmental Policy Act and other environmental laws and regulations.

§ 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). Individuals and systems that may be affected can be identified. Methodologies, strategies, and techniques employed to deal with the issues at hand are seldom new or untested. Alternative means of dealing with those issues are well established. Mitigation measures are generally available and have been successfully employed. 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;

(ii) Implementation of program plans at the site-specific, action level, except for actions that are categorically excluded, as provided in paragraph (c) of this section.

(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, except for actions that are categorically excluded, as provided in paragraph (c) of this section.

(4) Approvals and issuance of permits for proposals involving genetically engineered or nonindigenous species, except for actions that are categorically excluded, as provided in paragraph (c) of this section.

(5) Research or testing that:

(i) Will be conducted outside of a laboratory or other containment area (field trials, for example); or

(ii) 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) Pesticide treatments applied to infested plants at a nursery; and

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

(2) *Research and development activities.* (i) Activities that are carried out in laboratories, facilities, or other areas designed to eliminate the potential for harmful environmental effects—internal or external—and to provide for lawful waste disposal.

(ii) Examples of this category of actions include:

(A) The development and/or production (including formulation, repackaging, movement, and distribution) of

previously approved and/or licensed program materials, devices, reagents, and biologics;

(B) Research, testing, and development of animal repellents; and

(C) Development and production of sterile insects.

(3) *Licensing and permitting.* (i) Issuance of a license, permit, or authorization to ship for field testing previously unlicensed veterinary biological products;

(ii) Permitting, or acknowledgment of notifications for, confined field releases of genetically engineered organisms and products; and

(iii) 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) *Rehabilitation of facilities.* Rehabilitation of existing laboratories and other APHIS facilities, functional replacement of parts and equipment, and minor additions to such existing APHIS facilities.

(d) *Exceptions for categorically excluded actions.* Whenever the decisionmaker 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;

(3) When a previously unlicensed veterinary biological product to be shipped for field testing contains live microorganisms or will not be used exclusively for *in vitro* diagnostic testing; or

(4) 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]

§ 372.6 Early planning for applicants and non-APHIS entities.

Each prospective applicant who anticipates the need for approval of proposed activities classified as normally requiring environmental documentation is encouraged to contact, at the earliest opportunity, APHIS' program staff.

[60 FR 6002, Feb. 1, 1995; 60 FR 13212, Mar. 10, 1995]

§ 372.7 Consultation.

Prospective applicants are encouraged to contact APHIS program officials to determine what types of environmental analyses or documentation, if any, need to be prepared. NEPA documents will incorporate, to the fullest extent possible, surveys and studies required by other environmental statutes, such as the Endangered Species Act.

[60 FR 6002, Feb. 1, 1995; 60 FR 13212, Mar. 10, 1995]

§ 372.8 Major 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