§ 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 micro-organisms and extraneous material) that are not strains of quarantine concern and occur, or are likely to occur, in a State's environment; or

(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 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; 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]

§ 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