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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 372

Docket No. APHIS-2013-0049

RIN 0579-AC60

National Environmental Policy Act Implementing Procedures

AGENCY: Animal and Plant Health Inspection Service, USDA

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the regulations that set out our National Environmental Policy Act implementing procedures. The amendments include clarifying and amending the categories of action for which we would normally complete an environmental impact statement or an environmental assessment for an action, expanding the list of actions subject to categorical exclusion from further environmental documentation, and setting out an environmental documentation process that could be used in emergencies. The proposed changes are intended to update the regulations and improve their clarity and effectiveness.

DATES: We will consider all comments that we receive on or before [Insert date 60 days after date of publication in the Federal Register].

ADDRESSES: You may submit comments by either of the following methods:

- Federal eRulemaking Portal: Go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2013-0049>.

- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2013-0049, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

Supporting documents and any comments we receive on this docket may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2013-0049> or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

FOR FURTHER INFORMATION CONTACT: Dr. Elizabeth E. Nelson, APHIS Federal NEPA Contact, Environmental and Risk Analysis Services, PPD, APHIS, 4700 River Road Unit 149, Riverdale, MD 20737-1238; (301) 851-3089.

SUPPLEMENTARY INFORMATION:

Background

The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 et seq.), is the United States' basic charter for protection of the environment. The President's Council on Environmental Quality (CEQ) Regulations for Implementing the Procedural Provisions of the NEPA, published in 40 CFR parts 1500 through 1508 (referred to below as the CEQ regulations) regulate the implementation of NEPA across Federal agencies.

The Office of the Secretary of the U.S. Department of Agriculture (USDA) has set forth departmental policy on the implementation of NEPA in 7 CFR part 1b. Within USDA, the Animal and Plant Health Inspection Service (APHIS) has regulations that set out its procedures for implementing NEPA in 7 CFR part 372 (referred to below as the regulations). APHIS'

regulations are designed to ensure early and appropriate consideration of potential environmental effects when APHIS programs formulate policy and make decisions. The regulations also promote effective and efficient compliance with NEPA requirements and integration of other environmental review requirements under NEPA (e.g., 40 CFR 1500.2(c) and 40 CFR 1500.4(k)). Consistent with the requirements of the CEQ NEPA implementing regulations, the APHIS regulations supplement the CEQ regulations and the USDA NEPA implementing regulations to take into account APHIS missions, authorities, and decision-making. The APHIS regulations include definitions, categories of actions, major planning and decision points, opportunities for public involvement, and methods of processing different types of environmental documents.

The APHIS regulations were last amended in a final rule published in the Federal Register on February 1, 1995 (60 FR 6000–6005, Docket No. 93-165-3; corrected on March 10, 1995, at 60 FR 13212). The CEQ regulations at 40 CFR 1507.3(a) indicate that agencies "shall continue to review their policies and procedures and in consultation with the Council to revise them as necessary to ensure full compliance with the purposes and provisions of the Act." Since 1995, APHIS has begun several new types of actions (e.g., the Plant Protection Act of 2000) that are not covered in the current regulations, and gathered further data on the environmental impacts of those actions that are covered in the regulations. Accordingly, we have evaluated our regulations and identified changes that would reflect those new authorities, activities, and data. The changes we are proposing would also clarify certain areas of the regulations. APHIS has been and is consulting with CEQ regarding these changes, as required. In addition to reflecting APHIS' current responsibilities, the changes we are proposing reflect CEQ NEPA guidance that has been issued since the APHIS regulations were last amended. This guidance describes how

Federal agencies can establish, revise, substantiate, and apply categorical exclusions, and how agencies can periodically review categorical exclusions to assure that they remain useful.¹

NEPA and the CEQ regulations require all agencies of the Federal Government to include a detailed statement by the responsible official with every recommendation or report on proposals for legislation and other major Federal actions significantly affecting the quality of the human environment. This statement must cover:

- The environmental impact of the proposed action,
- Any adverse environmental effects which cannot be avoided should the proposal be implemented,
- Reasonable alternatives to the proposed action,
- The relationship between local short-term uses of man's environment and the maintenance and enhancement of long-term productivity, and
- Any irreversible and irretrievable commitments of resources which would be involved in the proposed action should it be implemented.

Such a detailed environmental statement is defined in the CEQ regulations as an environmental impact statement (EIS). The EIS is distinguished from the environmental assessment (EA), which is a concise public document that briefly provides sufficient evidence and analysis for determining whether to prepare an EIS or a finding of no significant impact (FONSI). Actions taken by an agency that do not individually or cumulatively have a significant effect on the human environment, may be categorically excluded from the requirement to prepare either an EA or an EIS.

¹ You may view the CEQ guidance document on the Internet at https://ceq.doe.gov/ceq_regulations/NEPA_CE_Guidance_Nov232010.pdf.

Proposed Reorganization

The CEQ regulations at 40 CFR 1507.3(b)(2) require agencies to develop specific criteria for and identification of those typical classes of action that normally require an EIS or an EA, as well as those that normally do not require further analysis in either an EIS or an EA and are thus categorically excludable actions. APHIS' regulations accomplishing this are currently found in § 372.5, "Classification of actions."

Since the last time the regulations were updated in 1995, APHIS has determined that many additional categories of APHIS actions can and should be categorically excluded. In addition, we are proposing to provide examples for broad categories of actions that would be categorically excluded and to further explain the process for using those categorical exclusions. For ease of reading, therefore, we are proposing to differentiate the categorical exclusions currently found in § 372.5 into new sections. These new sections would be numbered §§ 372.8 through 372.10 with 372.5 addressing environmental impact statements, 372.6 addressing environmental assessments, 372.7 addressing categorical exclusions in general, and 372.8 through 372.10 describing categorical exclusions. Consequently, current sections §§ 372.6 through 372.10 would be redesignated. The proposed sections are listed in Table 1, along with the paragraph in current § 372.5 to which they correspond.²

² A detailed accounting of the rationale for each of the proposed changes may be found in the document entitled "Proposed Amendments to National Environmental Policy Act Implementing Procedures (7 CFR part 372), Substantiating Document for Proposed Amendments," which is available on the Internet at <http://www.regulations.gov/#!docketDetail;D=APHIS-2013-0049>.

Table 1.—Current and proposed organization of categories of actions in APHIS’ NEPA regulations

Proposed section	Title	Current paragraph(s) in § 372.5
372.5	Actions normally requiring environmental impact statements	(a)
372.6	Actions normally requiring environmental assessments but not necessarily environmental impact statements	(b)
372.7	Categorical exclusions; general provisions	Introductory text of (c) and (d), (d)(1)
372.8	Categorical exclusions; conventional measures	(c)(1)
372.9	Categorical exclusions; licensing, permitting, and authorization or approval	(c)(3)
372.10	Categorical exclusions; other categories of actions	(c)(2), (c)(4)

Actions Normally Requiring Environmental Impact Statements

The introductory text of paragraph (a) of current § 372.5 sets out a description of actions APHIS takes that normally require environmental impact statements.

We are proposing to make several changes to the introductory text. First, we are proposing to refer to a category of actions rather than a class of actions. This change would be consistent with the CEQ regulations that use the phrase “category of actions.” We would make this change in the rest of our regulations as well.

Second, rather than referring to policymakings and rulemakings, we are proposing to simply refer to “actions.” APHIS takes actions that are not policymakings or rulemakings but which could nevertheless have a significant impact on the human environment and thus warrant an EIS. For example, APHIS’ Wildlife Services (WS) program prepared an EIS for gull hazard management actions at John F. Kennedy International Airport. These actions were not part of a policymaking or a rulemaking.

We also are proposing to modify the regulations to add several types of EIS eligible actions. The current text indicates that risks to animal and plant health are the only reasons APHIS takes action. However, APHIS takes other types of actions, including those that protect or preserve property, natural resources, and human health and safety. For example, under the Plant Protection Act (7 U.S.C. 7701 et seq.), APHIS may designate a plant as a noxious weed based on the damage it causes to irrigation, navigation, the natural resources of the United States, the public health, or the environment, and may take action to address the weed's harmful effects. APHIS' Wildlife Services program also undertakes actions to manage wildlife damage in order to promote or protect human health and safety, such as actions to mitigate against the risk of bird strikes on airplanes or rabies in wildlife. We would add these actions to the regulations.

The current text states that actions in this category are characterized by their broad scope and potential effect. We are proposing to qualify this statement by indicating that these characteristics typically characterize actions in this category. Sometimes, APHIS takes actions that have a broad scope, but whose impacts on the environment are not significant. The program to reduce the spread of rabies in wildlife is one example of such an action. The action may have a broad scope, but we can easily determine and characterize the likely potential effects as not significant.

We are proposing to provide more detail on what we mean by potential effects on the human environment. We would specify that, for the purposes of determining whether an action warrants an EIS, we are interested in the intensity of the potential effects, which refers to the severity of impact and is defined in 40 CFR 1508.27(b) where the regulations state that the following 10 factors should be considered in evaluating intensity: (1) Impacts that may be both beneficial and adverse. A significant effect may exist even if the Federal agency believes that on

balance the effect will be beneficial; (2) The degree to which the proposed action affects public health or safety; (3) Unique characteristics of the geographic area such as proximity to historic or cultural resources, park lands, prime farmlands, wetlands, wild and scenic rivers, or ecologically critical areas; (4) The degree to which the effects on the quality of the human environment are likely to be highly controversial; (5) The degree to which the possible effects on the human environment are highly uncertain or involve unique or unknown risks; (6) The degree to which the action may establish a precedent for future actions with significant effects or represents a decision in principle about a future consideration; (7) Whether the action is related to other actions with individually insignificant but cumulatively significant impacts. Significance exists if it is reasonable to anticipate a cumulatively significant impact on the environment.

Significance cannot be avoided by terming an action temporary or by breaking it down into small component parts; (8) The degree to which the action may adversely affect districts, sites, highways, structures, or objects listed in or eligible for listing in the National Register of Historic Places or may cause loss or destruction of significant scientific, cultural, or historical resources; (9) The degree to which the action may adversely affect an endangered or threatened species or its habitat that has been determined to be critical under the Endangered Species Act of 1973; and (10) Whether the action threatens a violation of Federal, State, or local law or requirements imposed for the protection of the environment. Instead of referring to environmental quality values, we would refer to environmental components, and give the examples of air, water, soil, plant communities, and animal populations. This change would add clarity to the regulations, as “environmental quality values” has proven to cause confusion. It would also increase transparency regarding those environmental elements we consider when writing an EIS. We would also provide an example of an indicator, including, but not limited to the dissolved oxygen

content of water. These would help the reader to understand the types of effects we consider to determine when to prepare an EIS.

We would remove the sentence that states that the use of new or untried methodologies, strategies, or techniques to deal with pervasive threats to animal and plant health would lead us to complete an EIS. The fact that a method is novel does not by itself mean its use will have significant environmental impacts warranting an EIS. For example, APHIS may develop a new method that involves noninvasive procedures or whose potential impacts, either positive or negative, are well understood. Neither of these actions would necessarily warrant an EIS.

We would also remove the sentence stating that, for actions that warrant an EIS, alternative means of dealing with a threat to animal and plant health usually have not been well developed. The presence or absence of alternatives by themselves does not determine the potential impacts an agency action would have on the human environment.

Paragraphs (a)(1) of § 372.5 currently lists “formulation of contingent response strategies to combat future widespread outbreaks of animal and plant diseases” as an action that might normally require an EIS. This category of actions is still appropriate, and we would retain it. Paragraph (a)(2) of § 372.5 would be slightly modified to read as follows: “Adoption of strategic or other long-range plans that prescribe a preferred course of action for future actions implementing the plan.” This modification more fully captures our intent that both the overarching strategic or long-range plan itself and actions taken to implement that plan should be considered in an EIS.

The current categories of action that normally require an EIS would be found in paragraphs (a) and (b) of proposed § 372.5.

Actions Normally Requiring Environmental Assessments But Not Necessarily Environmental Impact Statements

The introductory text of paragraph (b) of current § 372.5 sets out a description of actions APHIS takes that normally require environmental assessments but not necessarily environmental impact statements. It reads as follows:

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.

We are proposing to make this text the introductory text of a new § 372.6 and to make several changes to it.

The current text explains that "limited scope" means actions involving particular sites, species, or activities. We would expand this explanation to add State-wide or district-wide programs. We have found that agency actions of this scope can typically be adequately assessed in an EA. We would also indicate that activities may involve a specific species or similar species. We have found that impacts associated with actions involving multiple, similar species are not significantly different than actions involving a particular species.

We would expand the current discussion of potential effects. To contrast with our proposed text regarding actions that normally require an EIS, we would state that 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 previously been successful. Again, the intensity and likelihood of the potential effects are our primary concern.

We would remove the sentences discussing the novelty of methodologies, strategies, and techniques used to deal with issues and the alternative means of dealing with those issues, for the same reasons we would remove them in our discussion of the actions that normally require an EIS.

Finally, the regulations currently list several categories of actions as actions that normally require an EA but not necessarily an EIS. However, within those general categories, there are several specific categories of action that we have determined should be subject to categorical exclusions.

In current § 372.5, paragraphs (b)(1) through (b)(5) list specific categories of actions that normally require an EA but not necessarily an EIS. Along with our proposed move of these categories to § 372.6, we are proposing to remove one category, amend two of the other current categories, and add two new categories.

Current paragraph (b)(1) lists 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 as actions that would normally require an EA. We would move this category to paragraph (a) in proposed § 372.6 and add the word "actions" to "policymakings and rulemakings." This change would ensure that the regulations reflect the broad range of activities for which APHIS prepares environmental compliance documentation.

Paragraph (b)(2) of § 372.5 lists planning, design, construction, or acquisition of new facilities, or proposals for modifications to existing facilities as actions that would normally

require an EA. We would move it to paragraph (b) of proposed § 372.6, but would otherwise leave it unchanged apart from specifying that the substantial modifications to existing facilities under discussion are also included.

Paragraph (b)(3) of § 372.5 lists the disposition of waste and other hazardous toxic materials at laboratories and other APHIS facilities, except when categorically excluded, as normally requiring an EA. We would move it to paragraph (c) of proposed § 372.6, but would otherwise leave it unchanged.

Paragraph (b)(4) of current § 372.5 lists approvals and issuance of permits for proposals involving genetically engineered or nonindigenous species, except for actions that are categorically excluded, as normally requiring an EA but not necessarily an EIS. We are proposing to amend this category of action to include issuance of licenses, as well as permits, to reflect the terminology used by APHIS animal health and biotechnology programs as well as to specify that we are referring only to regulated genetically engineered or nonindigenous species. We would also move this category of action to paragraph (d) of proposed § 372.6.

We are proposing to add a new category of actions as paragraph (e) of proposed § 372.6. This paragraph would indicate that programs 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, management of rabies in wildlife, or protection of threatened or endangered species, normally require an EA but not necessarily an EIS. Such programs are managed by APHIS' WS program. Since 1994, WS has prepared and worked under hundreds of EAs for these types of program activities. WS' EAs for program activities include review of potential environmental impacts on target species, nontarget species including threatened and endangered species, aesthetic values, and any

additional issues identified through the NEPA process. WS monitors impacts of actions taken under these EAs to ensure that the EAs' analyses continue to adequately evaluate program goals, actions, and impacts. In no instance have WS' monitoring evaluations indicated that WS' actions under these types of EAs had impacts warranting preparation of an EIS.³ For these reasons, we believe it is appropriate to establish this category of actions as requiring an EA but not necessarily an EIS.

Paragraph (b)(5) of § 372.5 currently lists two examples of research and testing actions that normally require an EA: Research and testing that will be conducted outside of a laboratory or other containment area, and research and testing that reaches a stage of development (e.g., formulation of premarketing strategies) that forecasts an irretrievable commitment to the resulting products or technology. We are proposing to retain this category of action, as paragraph (f) of proposed § 372.6.

We would add a new category of action as paragraph (g): Determination of nonregulated status for genetically engineered organisms. Under current paragraph (b)(4) of § 372.5, APHIS has been preparing EAs when it determines a genetically engineered organism is not a plant pest risk and does not present significant environmental impacts. However, determining that a genetically engineered organism should not be regulated is not an action that fits within the category of an approval or an issuance of a permit or license; such actions are addressed in the corresponding proposed paragraph (d) of § 372.6. Adding this example as a separate paragraph would provide transparency and clarification about how APHIS addresses potential environmental impacts associated with actions on petitions for nonregulated status of genetically

³ For a current list and examples of active WS EAs, see http://www.aphis.usda.gov/regulations/ws/ws_nepa_environmental_documents.shtml.

engineered organisms as described in 7 CFR 340.6. The significance factors listed in 40 CFR 1508.27 are considered when determining the appropriate environmental documentation for these actions, and our NEPA analyses have repeatedly demonstrated that the level of potential environmental impact is usually not significant, making an EA appropriate for such actions unless the significance factors listed in 40 CFR 1508.27 apply.⁴

Categorical Exclusions; General Provisions

The bulk of the changes we are proposing to the regulations relate to categorical exclusions. When experience and monitoring indicate that an action or a type of action does not have a significant or substantial impact on the human environment, establishing a categorical exclusion for that action benefits both APHIS and the public. Most actions APHIS takes are designed to prevent damage or harm to animals, plants, and human enterprises related to those animals and plants. Making these actions subject to a categorical exclusion, when appropriate, in accordance with criteria in §§ 372.7 through 372.10, benefits the human environment by allowing APHIS to take action to prevent or reduce the damage or harm more quickly than would be possible if the agency had to complete an EA or EIS for the action.

Paragraph (a) of proposed § 372.7 would set out general provisions for APHIS' use of categorical exclusions. Currently, these provisions are found in the introductory text of paragraph (c) of § 372.5. We would make two changes to the current provisions. First, the introductory text of this paragraph currently states that categorically excluded actions are similar to actions that normally require an EA but not necessarily an EIS in terms of their extent of

⁴ You may view specific examples on the Internet at https://www.aphis.usda.gov/myportal/aphis/resources/lawsandregs/SA_Environmental_Protection/SA_Statutes/SupplementalNEPAAmendments.

program involvement and the scope and effect of and availability of alternatives to proposed actions. Because we are proposing to remove the text dealing with alternatives from the EIS and EA sections, we are proposing to remove it here as well.

In addition, paragraph (c) of § 372.5 currently states that the major difference between categorically excluded actions and actions that require an EA, but not necessarily an EIS, is that for categorically excluded actions, the means through which adverse environmental impacts may be avoided or minimized have actually been built into the actions themselves. The paragraph goes on to state that the efficacy of this approach generally has been established through testing and/or monitoring.

We are proposing to indicate that mitigation measures alone are not the sole key factor. Rather, there are several key factors that we should consider when determining whether a category of actions is categorically excluded, which are (1) the extent to which mitigation measures to avoid or minimize adverse environmental impacts have been built into the actions themselves and, in some cases, standard operating procedures; (2) Agency expertise and experience implementing the actions; and (3) whether testing or monitoring have demonstrated there normally is no potential for significant environmental impacts.

We would also add evaluation criteria which must be met prior to any determination of categorical exclusion. These would be found in new paragraphs 372.7(a)(1)(i) through (a)(1)(iii). The first evaluation criterion is to determine whether the action has not been segmented in order to meet the definition of a categorical exclusion. Segmentation may occur when an action is intentionally broken down into component parts in order to avoid the appearance of significance of the total action. The second evaluation criterion would be to determine whether any extraordinary circumstances exist that would require us to preclude the

use of a categorical exclusion. An example of an extraordinary circumstance would be when a proposed action that is normally categorically excluded may have the potential for significant adverse environmental impacts to nontarget species. The third evaluation criterion would be whether the action occurs in a limited area, does not permanently adversely affect the area, and is performed with well-established procedures (e.g., permits for GE organism field testing under specified conditions).

These changes would emphasize that actions we take do not individually or cumulatively have a significant effect on the environment, as demonstrated through long-term application or testing and monitoring, without the need to build in means to avoid or minimize environmental impacts. Many examples of such actions will be discussed later in this document.

Paragraph (d) of current § 372.5 discusses exceptions for categorically excluded actions and lists examples of such exceptions. As part of our reorganization of the list of actions subject to categorical exclusions, we are proposing to list common exceptions to categorical exclusions next to the categorical exclusions themselves in the regulatory text. We hope that this change would highlight the potential exceptions for users of the regulations. We are proposing to refer to such exceptions as "extraordinary circumstances," consistent with CEQ's instructions in the definition of "categorical exclusion" in 40 CFR 1508.4 to provide for "extraordinary circumstances in which a normally excluded action may have a significant environmental effect." (In § 372.4, which contains definitions of various terms used in the APHIS NEPA implementing regulations, we would add a definition of extraordinary circumstances, which would be consistent with the CEQ regulations.)

We would retain the introductory text of paragraph (d) of current § 372.5 as paragraph (b) of proposed § 372.7. It would continue to indicate that, whenever the Agency official

responsible for environmental review determines that a categorically excluded action may have the potential to significantly affect the quality of the human environment, an EA or an EIS will be prepared. (In § 372.4, which contains definitions of various terms used in the APHIS NEPA implementing regulations, we would add a definition of Agency official responsible for environmental review, which would be consistent with the CEQ regulations.)

We are also proposing to add a new paragraph § 372.7(c), which would describe the extraordinary circumstances for individual categorically excluded actions that would preclude the use of a categorical exclusion. A list of specific extraordinary circumstances for these actions would be provided in paragraphs (c)(1) through (c)(17).

Please note that the following sections include examples of activities that we expect would result in categorical exclusions. These lists are not intended to be comprehensive accounts of all possible categorical exclusions. Any activity not listed would still have to meet the requirements for a categorical exclusion.

Categorical Exclusions; Conventional Measures

Paragraph (c)(1) of § 372.5 currently lists various categorically excluded actions under the heading of "routine measures." We are proposing to list such measures, and explanations and examples of such measures, in a new § 372.8.

As described in current paragraph (c)(1), routine measures include 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. The designation of these measures as "routine" has caused some uncertainty among agency personnel and the public. Certain actions that APHIS performs on a regular basis may nonetheless require us to prepare an EA or EIS each

time we perform them, depending on the potential for the actions to significantly affect the human environment. What the current regulations describe is an action that occurs in a limited area, does not permanently adversely affect the area, and is performed in accordance with well-established procedures. We believe that a better description for such measures is “conventional.” Therefore, we are proposing to refer to such measures as conventional measures both in our proposed description of general extraordinary circumstances for conventional measures in proposed § 372.7(c) and in proposed § 372.8.

We are proposing to change the current list of conventional measures slightly. The current list includes sampling that does not cause physical alteration of the environment. We are proposing to instead refer to monitoring, including surveys and surveillance, that does not cause physical alteration of the environment. This terminology is more commonly used within and outside APHIS to describe these activities, which will be discussed in more detail later in this document.

Paragraph (c)(1) of current § 372.5 goes on to describe the appropriate use of chemicals and other products as part of routine measures. Specifically, it states that 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 certain criteria.

In paragraph (a) of proposed § 372.8, we are proposing to expand the list of substances that may be used as part of a conventional measure, subject to certain conditions, to include the use of pesticides, chemicals, drugs, pheromones, contraceptives, or other potentially harmful substances, materials, and target-specific devices or remedies.

APHIS uses contraceptives, such as GonaCon, to manage populations of animals and mitigate their impacts on the environment and natural resources. APHIS uses drugs, such as the nonlethal sedative alpha chloralose, to temporarily immobilize animals for relocation or other management. Previous APHIS NEPA evaluations concluded that normal use patterns of both contraceptives and drugs do not individually or cumulatively have a significant effect on the human environment based on the limited duration and scope of their use and the design of the contraceptives and drugs, which limit effects on nontarget species.

APHIS uses pheromones to control plant pests; the pheromones mask the chemical scent of the target organism, making it difficult for the organism to find mates and reproduce. As long as pheromones are used in accordance with Environmental Protection Agency (EPA) labeling requirements, we have found that they do not individually or cumulatively have a significant effect on the human environment.. In practice, we expect pheromones to have substantially less potential for adverse impacts than other chemical controls, given that they are highly species-specific and have extremely low toxicity to people and organisms (including target and nontarget organisms).

The introductory text of current § 372.5(c)(1) indicates that potentially harmful substances must be used according to any label instructions or other lawful requirements and consistent with standard, published program practices and precautions. We would retain this language in proposed § 372.8(a).

Paragraphs (c)(1)(ii)(A) through (c)(1)(ii)(C) of current § 372.5 contain three examples of routine measures. To assure clarity, we are proposing to explain in proposed § 372.8 every conventional measure listed in the introductory text and to provide examples of each conventional measure. These explanations and examples can be found in paragraphs (b) through

(l) of proposed § 372.8. The proposed lists of examples are intended to illustrate each of the conventional measures, not to be exhaustive. The proposed conventional measures and their explanations and examples are discussed below.

Identifications. Identifications would include detection and identification of premises or animals, or identification of organisms, diseases, or species causing damage or harm. These processes in and of themselves do not have any significant impacts on the human environment. Examples would include, but would not be limited to: Issuance of a specific identification number and application of commodity labels, animal tags, radio transmitters, microchips, and chemicals (such as tetracycline or rhodamine B ingestion).

Inspections. Inspections would include inspections of articles (including fruits and vegetables) to determine if there are any plant pests present, which could involve cutting fruit for inspection; the physical inspection of animals upon entry into the United States; facility and records inspections; or inspections of commodities, facilities, or fields, including paperwork and records, for approval and to assure compliance with regulations and program standards.

Inspections usually follow a prescribed protocol and document findings on an inspection report form. Examples would include, but would not be limited to, the physical examination of plants, plant products, and animals at the port of entry; review of containment facilities; and review of paperwork and records to assure compliance with program regulations and standards.

Inspection methods typically rely on visual observation or destruction of a small number of subsamples (for example, cutting of fruit to detect larvae) and do not individually or cumulatively have a significant effect on the human environment. Inspection of animals usually involves restraint, which is performed following established animal care and animal welfare guidelines. Inspection may also involve visual inspection of facilities, such as inspection of

facilities holding animals covered under the Animal Welfare Act to verify that the animals are being held in compliance with the regulations promulgated under that act, inspection of packinghouses to verify compliance with plant health regulations, or inspections of facilities performing animal health work. These activities are not expected to have any impact on the human environment, and years of data have indicated that they do not.

Monitoring, including surveys, surveillance, and trapping, that does not cause physical alteration of the environment. Surveys would include questionnaires to collect information and data to assess a current state or trend in activities, to determine compliance, or to determine whether a pest or disease exists in a specific area. Surveys are administrative processes only and thus do not individually or cumulatively have a significant effect on the human environment.

Surveillance would include activities to collect test samples from part or all of the target population using routine collection techniques. Monitoring and surveillance generally involves limited numbers of animals (relative to State and regional populations) and a limited area. If warranted, inspection may involve the collection of a biological sample for submission to a laboratory for diagnostic testing. The quantity of any biologic samples collected is negligible (for example, 2 to 5 milliliters of blood, a punch biopsy, or a swab). Monitoring chemical residue involves the collection of small samples of environmental components (for example, water, leaves, or soil) to test for the presence of a chemical. Sample collection occurs at limited locations and times. These are standard practices used by scientists daily with no impact to the environment being sampled or to people.

Trapping would be described as the use of capture devices that are designed to efficiently capture, restrain, or kill targeted individual animals or a group of animals (e.g., fruit flies and other insects, a raccoon, a sounder of feral swine). Capture devices used in trapping would be

described as foothold; cage; drive; quick-kill; pit (for insects and some small rodents, reptiles and amphibians); insect and sticky traps; snares and other cable restraints; nets; hands; contained animal drugs (e.g., dart guns, tranquilizer tab devices); and insecticides. Attractants used with some types of trapping are food, odor baits or lures, pheromones, shapes, and colors. Only organisms that become caught in the trap are affected. While some nontarget captures may be inevitable, the design of the traps minimizes this effect. Nevertheless, the capture of even a small number of federally listed threatened or endangered species is of concern. To address such captures, APHIS would conduct an Endangered Species Act (ESA) analysis. If the ESA analysis and other NEPA reviews indicate that the viability of a nontarget species population could be affected, we would prepare an EA for trapping.

Examples of these activities would include, but would not be limited to:

- Collection of biological or environmental samples such as tissue, soil, or water samples and samples of fecal matter.
- Continual checking, by testing, trapping, or observing for the presence, absence, or prevalence of animals, pests, or disease. This information may be used to support a pest or disease status (such as pest-free or disease-free status).
- Surveying and monitoring for disease may or may not require the lethal removal of the animal and can often be conducted using nonlethal methods, such as collection of samples from animals killed or removed for reason related to disease monitoring (i.e., damage management action addressed in an EA, or hunter-killed animals).
- Randomly selecting animals and obtaining blood samples to survey for disease, or collection of test samples.

Testing. Testing would be described as the examination or analysis of a collected sample. This activity often occurs in a laboratory, but also includes nonlethal tests that require animal-side or chute-side injection and observation in the field. Testing may require the use of specialized equipment and/or diagnostic test kits. APHIS programs conduct testing using standard operating procedures that are designed to eliminate the potential for harmful environmental effects, and years of monitoring have indicated that testing itself does not have any effect on the human environment. Examples would include, but would not be limited to, intradermal tuberculosis testing of livestock and germplasm testing of plant material for viral infections.

Seizures. Seizures would include taking possession of conveyances, materials, regulated articles, plants and plant products, animals and animal products, other articles infested with a pest or determined to be diseased or exposed to a disease, a regulated article that is mixed in a commodity, or contaminated shipping material. APHIS programs seize articles to prevent the importation or interstate movement of articles that could introduce or spread pests or diseases, or to prevent the movement of articles whose movement is not authorized because its risk has not been determined. The act of seizing an article simply results in a change of the entity with control of the article and, in itself, has no significant impacts on the environment. Examples of seizures would include, but would not be limited to:

- Confiscation of a commodity that could be a vector for a plant or animal disease or pest, or an animal or plant determined to be infested, infected, exposed, or not in compliance with APHIS regulations (such as one moved illegally or without proper paperwork).
- Seizure of a nonregulated commodity, seed, or propagative material containing regulated genetically engineered material.

Quarantines. Quarantines would be described as actions to restrict or prohibit movement from an area, including the creation, expansion, removal, or modification of quarantines. Stopping or otherwise restricting the movement of animals, plants, or other regulated articles has no impact on human health or the environment and therefore falls within the definition of “categorical exclusion” in 40 CFR 1508.4.

The proposed regulations would state that the establishment of a quarantine can include mitigations to allow for movement of animals or commodities while preventing the spread of the animal or plant pest or disease; for example, we may require chemical treatment of regulated articles that are moved from the quarantined area to ensure that the articles do not spread a pest. Such mitigations would be evaluated separately from the establishment of the quarantine itself, which would be covered by this categorical exclusion.

Examples of quarantines are:

- Quarantine of an area in which a pest or disease is known to occur to prevent movement of animals, plants, or other articles whose movement could spread the pest or disease.
- Changes in pest or disease status for an area or country, such as expansion or rescission of existing quarantines.
- Removal of quarantine restrictions when APHIS determines that it is appropriate to do so.

Removals. Removals would include the relocation or lethal removal of living organisms, or destruction of materials. Only when the magnitude and scope of the removal is limited would a removal qualify as a categorical exclusion, among other things. In such circumstances, removals do not individually or cumulatively have a significant impact on the human environment. (As noted earlier, an EA or EIS would be prepared when any conventional

measure, the incremental impact of which, when added to other past, present, and reasonably foreseeable future actions, has the potential for significant environmental impact.)

Some of the examples for removals would indicate the specific circumstances in which a removal would qualify for a categorical exclusion. In addition, a few of the proposed examples of removals have extraordinary circumstances in which they would not be eligible for a categorical exclusion.

Examples of removals that qualify for a categorical exclusion would include, but would not be limited to:

- Removal of animals in accordance with permits and agreements from the appropriate management agencies, or otherwise in accordance with regulations governing management of a species, for the purpose of approved research studies, surveillance and monitoring, or disease or damage management, or due to pest concerns. Such movement is typically for quarantine or testing purposes. Most confirmed cases of disease involve a very limited number of animals; therefore, the impact to the total population is negligible, especially in comparison to the potential number of animals that could be affected if the diseased animals are not removed.

- Removal of animals or material from premises.
- Removal of trees or shrubs and plants.
- Disposal or destruction of materials for which the Agency has regulatory authority due to, for example, completion of acknowledged or permitted activities, completion of regulated activities, or noncompliance and disposal of animals. This could include disposal of regulated articles (fruit, meat, regulated genetically engineered organisms, etc.) at ports of entry designated by U.S. Customs and Border Protection. Approved methods of disposal would range from burial, feeding to animals, composting, to co-burning for power generation. These removals

would be considered on a case-by-case basis and only when they are standalone actions, not tied to additional control activities on a larger scale.

- Routine disposal of carcasses using other approved methods, such as donation for human consumption, composting, chemical digestion, burial, and incineration. Carcass and waste material disposal is conducted in appropriately licensed and approved facilities, or in accordance with appropriate Federal, State and local restrictions and regulations, so any impact to human health, animal health, or the environment has been mitigated.

- Depopulation of domestic livestock and captive wildlife due to the presence of an animal disease or the reasonable suspicion of the presence of an animal disease. An extraordinary circumstance would apply, and we would prepare an EIS, if an outbreak of an animal disease would require the depopulation of a large number of animals potentially resulting in substantial or significant adverse impacts on the human environment.

Sanitizing, cleaning, and disinfection. This category of actions would include treatment of an infested commodity (such as fruits or vegetables), cleaning and disinfection that occurs when a disease is found or there is an emergency disease outbreak, treatment of a regulated article, or treatment of carcasses for disposal. Any treatment or cleaning and disinfection that uses chemicals, pesticides, or other products would have to be conducted in accordance with the criteria for the use of such substances at the beginning of proposed § 372.8 in order to be eligible for a categorical exclusion. Since such products are used in accordance with applicable label instructions, there should be no significant impact on the human environment. Nonchemical treatments, such as cold treatment or hot water dip treatment, are conducted in enclosed, temperature-controlled environments that do not affect the natural environment. Examples of sanitizing, cleaning, and disinfection would include, but would not be limited to:

- Treatment of regulated articles at existing facilities, such as irradiation treatment and methyl bromide special use treatment. For example, irradiation treatment is conducted in approved facilities that must be approved by other Federal and State agencies as sufficiently isolated from the surrounding environment that the use of irradiation does not have a significant impact.

- Treatment of a facility, container, or cargo hold at the port of entry to mitigate pest threats.

- Cleaning and disinfection of equipment, cages, facilities, or premises.

- Treatment of animal carcasses, using methods such as incineration, alkaline digestion, or rendering as a method to devitalize infectious material.

Inoculations. An inoculation would be described as the introduction of a pathogen or antigen into a living organism in order to invoke an immune response to treat or prevent a disease. Inoculations are administered to individual identifiable organisms at limited locations and times to produce internal immune responses. The limited scope and timespan of inoculations means that they do not individually or cumulatively have a significant effect on the human environment. Examples are:

- 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).

- Use of vaccinations or inoculations, including new vaccines (including 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. An extraordinary circumstance would apply if 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. (This extraordinary circumstance comes from current paragraph (d)(2) of § 372.5.)

Animal handling and management. This would include nonlethal methods not addressed elsewhere in part 372 that are used to prevent, monitor for, reduce, or stop disease, damage, or harm caused by animals. (Some animal handling and management methods, such as removal and testing, are addressed earlier in proposed § 372.8.) APHIS' WS program has conducted many EAs examining the use of nonlethal animal handling and management methods in the context of State-wide programs. These EAs concluded that such methods have no significant impact on the human environment and resulted in FONSI's. Similarly, APHIS' Veterinary Services (VS) program may require livestock producers within quarantined areas to use generally accepted biosecurity practices as part of a disease control or eradication program. As these practices are designed to prevent the spread of animal disease, and as they are conducted in accordance with applicable Federal, State, and local regulations, they do not have a significant impact, as demonstrated by the findings of VS's EAs and FONSI's. Examples of animal handling methods included in this categorical exclusion include, but are not limited to:

- Restraining or handling livestock, poultry, or wildlife to facilitate examination or other activities.
- Cultural methods and basic habitat management such as nonlethal management activities such as removal of food sources, modification of planting systems, modification of animal husbandry practices, water control devices for beaver dams, limited beaver dam removal, and pruning trees.

- Site-specific applications of nonlethal wildlife damage management practices such as frightening devices, exclusion, capture and release, and capture and relocation.

Recordkeeping and labeling. This categorical exclusion would cover requiring regulated parties to keep records demonstrating compliance with APHIS requirements or to label regulated articles to indicate compliance or set out restrictions on the movement of the article.

Recordkeeping and labeling are used as part of other measures or programs to ensure documentation of events in compliance with the regulations and other requirements.

Recordkeeping and labeling thus facilitate compliance and enforcement. Such activities involve paperwork only and thus are not expected to have an impact on the human environment.

Examples include, but are not limited to requiring regulated parties to:

- Maintain records documenting the results of trapping for insects.
- Maintain records of the application of treatments.
- Prepare labels indicating that the movement of a regulated article to certain areas within the United States is illegal.

- Retain records at approved livestock facilities and listed slaughtering or rendering establishments under 9 CFR part 71.

Categorical Exclusions; Licensing, Permitting, Authorization, and Approval

Paragraph (c)(3) of § 372.5 currently lists various categorically excluded actions under the heading of "licensing and permitting." We are proposing to list such actions, expanded to include authorizations and approvals as well as licensing and permitting, in a new § 372.9.

The introductory text of proposed § 372.9 would indicate that licensing and permitting refers to the issuance of a license, permit, or authorization to entities, including individuals, manufacturers, distributors, agencies, organizations, or universities for field testing,

environmental release, or importation or movement of animals; plants; animal, plant, or veterinary biological products; or any other regulated article. Authorization and approval would be for an entity to participate in a program or perform an action.

Generally, APHIS has put in place restrictions on the importation and interstate movement of many articles to prevent the introduction or dissemination within the United States of animal and plant pests and diseases. Decisions to allow the importation or interstate movement of such articles are made only after determining that any risk presented by the movement of the article has been adequately mitigated. Such actions therefore would not be expected to have a significant impact on the human environment.

APHIS also licenses, authorizes, or approves entities to carry out activities to further their purposes or goals. Such licensing, authorization, or approval is done only when APHIS has determined that the entity will effectively fulfill its designated responsibilities. These actions are administrative for the agency, and generally occur in support of actions that undergo programmatic analysis in an EIS or EA. To require a separate NEPA analysis for each license, authorization, or approval would not allow expedient action to serve the public, and would promote piece-meal analyses. Even collectively, these licenses, authorizations, and approvals are not expected to individually or cumulatively have significant effect on the human environment because they are part of programs where mitigations reduce potential effects.

We are proposing to list specific examples of these actions, organized by APHIS program area, in paragraphs (a) through (c) of proposed § 372.9. Paragraph (a) would set out examples of animal health-related actions. These are:

- Approval of interstate movement or importation of animals via regulations or permits.

APHIS' VS program approves such movement based on the requirements set forth in the Federal

disease program regulations as reflected in the 9 CFR. Risk assessments provide the basis for determining the requirements. Examples of how VS issues approvals would include:

- Use of permits to control the interstate movement of restricted animals, such as issuance of an official document or a State form allowing the movement of restricted animals to a particular destination.
- Use of permits for entry, such as pre-movement authorization for entry of animals into a State from the State animal health official of the State of destination.
- Approval of international movements through the use of import and export health certificates and import or export movement permits.
- Authorization to move animals out of the quarantine or buffer zone for cattle fever ticks by documentation (a State form) that confirms the animals have been inspected and found to be tick-free.
- Licensing of swine garbage feeding operations. This licensing occurs after a site visit finds and documents that all applicable requirements (9 CFR part 166 – Swine Health Protection) have been met, ensuring that the operations will conduct this activity properly and thus will have no impact on the human environment.
- Accreditation of private veterinarians. VS accredits veterinarians only if they are licensed and only after they complete an orientation, certify that they can complete certain tasks, and meet other requirements.
- Approval and permitting of laboratories to conduct official tests. VS approves laboratories to conduct official tests only after a site visit verifies that the tests are being conducted, recorded, and reported properly. Proper testing procedures reduce the overall

likelihood that an animal disease could have an impact on the human environment by ensuring correct and timely identification of disease threats.

- Approval of identification manufacturers to produce identification, tests, and identification devices.
- Listing of slaughter and rendering establishments for surveillance under 9 CFR 71.21.

The regulations in 9 CFR 71.21 require listed establishments to allow personnel from APHIS and the USDA's Food Safety and Inspection Service to conduct surveillance at the establishments.

- Approval of herd and premises plans that have environmental or waste management components. VS develops herd and premises plans in response to findings of disease in a herd or on a premises. The plans are designed to ensure that the herds remain disease-free and that animals can be safely introduced or reintroduced to the premises. Herd and premises plans may include cleaning and disinfection requirements. All cleaning and disinfection performed with cleaners and chemical disinfectants would need to be in compliance with our proposed requirements for the use of such substances as part of conventional measures, discussed earlier in this document. Herd and premises plans may also include environmental and waste management requirements to address the presence of disease, such as the removal of all manure, some removal of a certain depth of topsoil in a feedyard, spreading of lime on the soil to make the soil too basic for the organism to survive, or, as is often recommended, simply letting the pastures lay dormant (without livestock) and exposed to natural sunlight to assure elimination of the disease organism over time. For the reasons mentioned above, these practices are not expected individually or cumulatively to have a significant impact on the human environment.

- Approval of herd accreditation for tuberculosis or certification for brucellosis to document the herd's freedom from disease. This is an administrative action that poses no adverse impacts to the environment.
- Funding the depopulation of diseased herds, including indemnity and carcass disposal; authorization and funding of the collection and submission of tissue samples for testing. These are decisions that allow VS to undertake certain conventional measures described in proposed § 372.8, such as removals and implementation of biosecurity methods.
- Approval of participation in the National Poultry Improvement Plan (the Plan) by issuance of a permanent approval number in accordance with 9 CFR 145.4. This is an administrative action taken after VS has determined that a flock owner is qualified to participate in the Plan.
- Currently, paragraph (c)(3)(i) of § 372.5 sets out a categorical exclusion for the issuance of a license, permit, or authorization to ship for field testing previously unlicensed veterinary biological products. We are proposing to amend this categorical exclusion in several ways. First, we are proposing to separate authorization to ship for field testing from issuance of a license or permit. Typically, field testing must occur before a license or permit can be issued, assuming the veterinary biological product meets the requirements of the regulations. We would list these actions in two separate categorical exclusions. Second, we would expand these categorical exclusions to explicitly include previously unlicensed veterinary biological products containing genetically engineered organisms, such as vector-based vaccines and nucleic acid-based vaccines. Although such field testing could be considered to be included in the current categorical exclusion, VS' Center for Veterinary Biologics (CVB) has been completing EAs for such activities as a matter of policy, due to uncertainty about the environmental effects

associated with the use of genetically engineered organisms. Accordingly, CVB has completed risk assessments and EAs for numerous vaccines containing genetically engineered organisms. The routine licensing requirements of CVB, which apply to these vaccines as well, ensure the vaccines' purity, identity, safety, potency, and efficacy. All of the EAs prepared for vaccines containing genetically engineered organisms have resulted in findings of no significant impact, and subsequent monitoring has not identified any impact these vaccines have had on the human environment. Accordingly, we believe it is appropriate to include these types of vaccines in the proposed categorical exclusions. The new categorical exclusions would read: "Authorization to ship and field test previously unlicensed veterinary biologics including veterinary biologics containing genetically engineered organisms (such as vector-based vaccines and nucleic-acid based vaccines)" and "Issuance of a license or permit for previously unlicensed veterinary biologics including veterinary biologics containing genetically engineered organisms (such as vector-based vaccines and nucleic-acid based vaccines)." Such categorical exclusions are based on field safety data and laboratory testing conducted since CVB's inception in 1976. In addition, just because an action qualifies for a categorical exclusion, it will be examined. In the unlikely event that there were a vaccine with GE organisms that were deemed likely to significantly impact the human environment, the EA process would be initiated.

- Current paragraph (d)(3) of § 372.5 provides an extraordinary circumstance for the issuance of licenses, permits, or authorizations for shipping and field testing previously unlicensed veterinary biologics. The extraordinary circumstance applies when a previously unlicensed veterinary biological product to be shipped for field testing contains live micro-organisms or will not be used exclusively for in vitro diagnostic testing. However, as described above, we have prepared extensive environmental documentation for the testing of such products

and have not found there to be a significant impact on the human environment. Accordingly, we are not including this extraordinary circumstance in the current proposal.

- Currently, paragraph (c)(3)(iii)(C) of § 372.5 sets out a categorical exclusion for permitting of releases into a State's environment of pure cultures of organisms that are either native or are established introductions. With respect to VS activities, the term "pure cultures" refers to seeds that are used to manufacture veterinary biologics. In accordance with the definition of "pure" found in 9 CFR 101.5(c), they must be tested as determined by test methods or procedures established by APHIS and found relatively free of extraneous micro-organisms and extraneous material (organic or inorganic).

We are proposing to make minor changes to this categorical exclusion. First, we would indicate that the issuance of any license, permit, authorization, or approval for the use of a pure culture would be subject to a categorical exclusion, to cover all possible uses. Second, we would add a parenthetical explaining that pure cultures are relatively free of extraneous micro-organisms and extraneous material. Third, rather than refer to cultures that are "native or established introductions," we would instead refer to cultures that occur or are likely to occur in a State's environment. It is not necessary for the purposes of assessing environmental impact to distinguish between native organisms and established introductions of organisms, since both occur in the environment, making it unlikely for the release of a pure culture to have environmental impacts. We would determine whether an organism is likely to occur in a State based on the known distribution of the organism, environmental factors, and any other available evidence. For example, if an organism is present in all the surrounding States, it is likely to occur in the surrounded State even if the organism has not been reported there. The use of a pure culture of an organism in a State where the organism is likely to occur is not expected to have

significant environmental effects due to the presumed previous presence of the organism.

Finally, we would add a qualifier to the existing categorical exclusion indicating that the release of a pure culture of an organism would not qualify for a categorical exclusion if the organism is of quarantine concern. Organisms of quarantine concern are typically subject to control or eradication efforts to prevent impacts on the environment, and releases of pure cultures of such organisms could hinder such efforts.

The revised categorical exclusion would read: "Issuance of a license, permit, authorization, or approval for 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."

- Issuance of permits and approval of facilities to import, transport, introduce, or release live animals and products or byproducts thereof, or other organisms for which proven risk mitigation measures are applied and will require no substantial modification for the specific articles under consideration. This would include importation or interstate movement of meat, milk/milk products, eggs, hides, bones, animal tissue extracts, etc., which present no disease risk or for which there are proven animal disease risk mitigation measures, such as heating, acidification, or standard chemical treatment. VS has developed common mitigations for many diseases, including sourcing only from healthy animals and from regions free of diseases of concern, quarantine and testing samples for evidence of disease, laboratory containment, and product processing procedures such as heating (including cooking or pasteurization), acidification, curing, storage, standard chemical treatment, and purification. VS conducts extensive monitoring of animal diseases to verify the efficacy of its disease mitigation approaches.

Paragraph (b) of proposed § 372.9 would set out examples of plant health-related actions that would be categorically excluded. These would include, but would not be limited to:

- Issuance of permits under 7 CFR part 330 for the importation or interstate movement of organisms into containment facilities, for the interstate movement of organisms between containment facilities, and continued maintenance and use of these organisms. The regulations in 7 CFR part 330 govern the importation and interstate movement of plant pests. Such pests, when imported or moved interstate, must be moved into containment facilities designed to prevent the escape of the pests into the surrounding environment. APHIS' Plant Protection and Quarantine (PPQ) program also amends permits to allow permit holders to continue to keep pests at the facility to which they have been transported. PPQ operates a compliance and enforcement program that involves reporting, periodic inspections, and consequences for variance from required features and procedures, up to and including destruction of organisms. In the last decade, there has been no evidence indicating that the issuance of such permits has any adverse environmental impacts. Therefore, the continued permitting for the importation and interstate movement of organisms in accordance with 7 CFR part 330 is not expected to have significant environmental effects.

- Issuance of permits for the use of organisms biologically incapable of persisting in the permitted environment. PPQ may permit the use of organisms under 7 CFR part 330 based on the environment surrounding the facility and using information about distribution, biology, and climate tolerances of organisms to ensure mismatch to the climate and season of release. For example, tropical organisms might be subject to a winter study in a greenhouse, or field study only in northern, temperate areas. Because the organisms are unable to persist in the permitted

environment and are maintained in compliance with permit conditions, issuance of the permits is not expected individually or cumulatively to have a significant effect on the human environment.

- As noted earlier, paragraph (c)(3)(iii)(C) of § 372.5 currently provides a categorical exclusion for permitting of releases into a State's environment of pure cultures of organisms that are either native or are established introductions. Besides veterinary biologics, this categorical exclusion also applies to release of pure cultures of organisms to be released as biological control agents. However, the activities have some major differences, and we are therefore proposing to separate the current categorical exclusion into two separate exclusions. In the area of biological control, a "pure culture" is loosely defined to include field collections of predators and parasites that are identified on sight as the desired organism. There is no reason or need to "sterilize" or remove contaminants prior to re-release.

Rather than refer to cultures that are "native or established introductions," we would instead refer to organisms that occur, or are likely to occur, in a State's environment. For the purposes of assessing environmental impact, distinguishing between native organisms and established introductions of organisms would require identification of distinguishing traits. These types of traits may not exist, and even if they do exist, would require specific testing to confirm.

Additionally, gaps in the reported distributions in the scientific literature remain because often there are few incentives to publish "new finds" of an organism in a State. Based on the last decade of permitting experience, when contiguous States have confirmed reports of the organism, the release of that organism into a nearby State lacking confirmed reports is not expected to have significant environmental effects. For these types of permits, we would continue to determine whether an organism is likely to occur in a State based on the known distribution of the organism, environmental factors, and any other available evidence.

We would not categorically exclude the release of an organism of quarantine concern.

Organisms of quarantine concern typically are subject to control or eradication efforts to prevent impacts on the environment, and releases of these organisms could hinder such efforts. We would restrict the permitted use of organisms of quarantine concern to containment facilities for research purposes.

Finally, besides the movement of pure cultures, other organisms may also be moved interstate for field release, for purposes such as field research outside containment facilities. PPQ only permits such movement when the organism occurs or is likely to occur in a State's environment; as described above, the movement of an organism to a State where PPQ has determined it is likely to occur is not expected to have a significant impact on the human environment, and has not over the past decade. As these two processes are similar, we would address them in the same categorical exclusion.

Therefore, the new plant health-specific categorical exclusion would read: “Issuance of permits for uses outside of containment that are pure cultures of organisms and that are not strains of quarantine concern and occur or are likely to occur in a State’s environment, and issuance of permits for the interstate movement of organisms that occur or are likely to occur in a State's environment.”

- Issuance of permits or approvals for the importation of articles that are regulated due to plant health concerns, when the permit contains conditions that will mitigate any plant pest risk associated with the articles. PPQ issues permits and approvals for the importation of plants, plant products, and other articles that could introduce quarantine pests into the United States. PPQ does so only after determining that any risk associated with the importation of the articles has been mitigated, thus ensuring that the importation would not have a significant impact on the

human environment. Mitigations are typically conventional measures, as described in proposed § 372.8; if mitigations have impacts on the human environment, their use would be evaluated separately from the decision to issue a permit to ensure that appropriate NEPA documentation is completed.

- Issuance of certificates or limited permits for the movement of regulated articles from areas quarantined due to plant pests. PPQ establishes domestic quarantines for quarantine pests and conditions for the movement of articles that could spread those pests under its regulations in 7 CFR parts 301, 302, and 318. Similar to importation of articles, PPQ issues certificates or limited permits for the interstate movement of such articles only after determining that any risk associated with the importation of the articles has been mitigated, thus ensuring that the movement would not have a significant impact on the human environment.

- Issuance of permits for the importation or interstate movement of noxious weeds and other regulated seeds. PPQ designates certain plants as noxious weeds in accordance with the Plant Protection Act (7 U.S.C. 7701 *et seq.*). The regulations in 7 CFR part 360 require permits for the importation and interstate movement of regulated noxious weeds. PPQ only issues permits when conditions are available to prevent the release of the regulated noxious weed into the environment, thus mitigating any potential risk to the environment. Similarly, PPQ enforces certain restrictions on the importation of seed under the Federal Seed Act and under the regulations in 7 CFR part 361. PPQ's enforcement of these restrictions mitigates any risk to the human environment that could arise from these importations.

- Issuance of permits for prohibited or restricted articles unloaded and landed for immediate transshipment or transportation and exportation. Transshipment or transportation and exportation of restricted articles is regulated under 7 CFR part 352. Permits for such movement

are granted only when sufficient safeguards are in place to prevent any plant pests that may have infested the shipment from being introduced into the United States. This ensures that such activities do not have any effect on the human environment.

Paragraph (c) of proposed § 372.9 would set out examples of biotechnology-related actions that would be categorically excluded. These would include, but would not be limited to:

- Issuance of permits for the importation, interstate movement, or environmental release of regulated genetically engineered organisms, provided that confinement measures (the permit conditions or performance measures), such as isolation distances from compatible relatives, control of flowering, or physical barriers, minimize the interaction of the regulated article with the environment. APHIS' Biotechnology Regulatory Services (BRS) program issues permits for importation or interstate movement of such articles only after determining that any risk associated with the importation or interstate movement of the articles has been sufficiently mitigated, thus ensuring that the importation or movement would not have a significant impact on the human environment. The regulations in 7 CFR part 340 govern the issuance of permits for the importation and interstate movement of certain genetically engineered organisms and products. Confinement measures are included in the permits; the confinement process is designed to ensure that the environmental release will not have a significant impact on the human environment.

Current paragraph (d)(4) of § 372.5 indicates that an extraordinary circumstance will apply when a confined field release of genetically engineered organisms or products involves new species or organisms or novel modifications that raise new issues. We are proposing that an extraordinary circumstance would apply when new permit conditions are included to address uncertainty about whether existing confinement measures will be sufficient to prevent the

interaction of the genetically engineered organism with the environment. We believe the added specificity of our proposed extraordinary circumstance will better communicate the types of concerns that might lead us to prepare an EA for a confined field release.

- Extension of nonregulated status under 7 CFR part 340 to organisms similar to those already deregulated. The regulations in that part allow for an applicant to request an extension or for BRS to initiate an extension based on the similarity of a regulated organism to an antecedent organism that has been deregulated. BRS then examines information and assesses whether the regulated article in question raises no serious new issues meriting a separate review under the petition process. Because requests for extensions of nonregulated status assess regulated articles that are similar to the deregulated antecedent organism, the regulated article is presumed to interact with the environment in the same way as the antecedent. EAs for extensions of nonregulated status incorporate the antecedent organism as part of the baseline or no action alternative. We have completed nine EAs for extensions of nonregulated status since 2000. Because the regulated organism (the subject of the request) is so similar to non-regulated organisms that are currently in the environment, the EAs have found no difference with respect to the impacts on biological or physical environment between the two organisms. Moreover, all of the assessments have resulted in findings of no significant impact. For these reasons, we believe it would be appropriate to establish a categorical exclusion for this category of actions.

- Notifications for environmental release, importation, or interstate movement of articles regulated under 7 CFR part 340. The notification process is described in 7 CFR 340.3. It is an administratively streamlined alternative to a permit for the introduction of an article regulated under that part. The article must meet certain eligibility criteria designed to reduce risk, and the

introduction must meet six performance standards. These include confinement and devitalization methods that are designed to further mitigate potential environmental impacts, if any.

Categorical Exclusions; Other Categories of Actions

Paragraph (c)(2) of § 372.5 currently lists various categorically excluded actions under the heading of "research and development." In addition, paragraph (c)(4) provides a categorical exclusion for the rehabilitation of APHIS facilities. As the descriptions of these categorical exclusions are not as extensive as the descriptions of conventional measures and of licensing, permitting, and authorization or approval, we are proposing to combine these categories of actions and list them in a new § 372.10.

Paragraph (c)(2)(i) of §372.5 currently provides a description of research and development activities; we are proposing to provide this description in the introductory text of paragraph (a) of proposed § 372.10. Such activities are currently described as 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.

We are proposing to make a few changes to this text. We would indicate at the beginning of this description that research and development activities that would be eligible for a categorical exclusion under proposed § 372.10 are those limited in magnitude, frequency, and scope. This would clarify why research and development activities usually have minimal effects on the environment.

Paragraph (c)(2)(ii) of current § 372.5 lists three examples of research and development activities that are categorically excluded:

- The development and/or production (including formulation, repackaging, movement, and distribution) of previously approved and/or licensed program materials, devices, reagents, and biologics;

- Research, testing, and development of animal repellents; and
- Development and production of sterile insects.

We are proposing to amend these examples and add three more in paragraphs (a)(1) through (a)(6) of proposed § 372.10.

Paragraph (a)(1) would provide a new categorical exclusion for vaccination trials that occur on groups of animals in areas designed to limit interaction with similar animals, or that include other controls needed to mitigate potential risk. The study design in these cases eliminates the potential for impacts on organisms other than the test subjects.

Paragraph (a)(2) would provide a new categorical exclusion for the evaluation of uses for chemicals not specifically listed on the product label, as long as they are used in a manner designed to limit potential effects to nontarget species such that there are no individual or cumulative impacts on the human environment. Such evaluation is necessary to determine whether chemicals may be effective against organisms not listed on the label as targets, or whether means of applying the chemical other than those listed on the label may be effective and safe. Many of these evaluations will be subject to experimental use permits issued by EPA with associated conditions to limit potential effects such that there are no individual or cumulatively significant impacts on the human environment. Other evaluations may have products that have been identified by EPA as minimum risk and therefore do not require a full Federal Insecticide, Fungicide, and Rodenticide Act registration. However, APHIS still does an environmental review to ensure safe use and no extraordinary circumstances.

Paragraph (a)(3) would expand on the current categorical exclusion that applies to the development and/or production of certain articles. We would amend this exclusion to include the development and/or production of program materials, devices, reagents, and biologics that are for evaluation in confined animal, plant, or insect populations under conditions that prevent exposure to the general population (e.g., conducted in laboratories or other facilities with established environmental and human safety protocols). Since the use is limited and the general population should not be exposed, the development or production of these articles would not have a significant impact on the human environment.

Paragraph (a)(4) would provide a new categorical exclusion for research using chemicals, management tools, or devices to test the efficacy of methods; new vaccinations not currently approved to test in the natural environment; the use of mechanical devices (such as noise and light deterrence); and existing vaccinations, chemicals, or devices used in a new way on an animal, pest, or disease similar to those on which they have previously been used.

Paragraph (a)(5) would expand on the current categorical exclusion for the research, testing, and development of animal repellents. As amended, the categorical exclusion would include all research related to the development and evaluation of wildlife management tools, such as animal repellents, scare devices, fencing, and pesticides. As indicated in the introductory text of proposed paragraph (a), APHIS research using the methods described in proposed paragraphs (a)(4) and (a)(5) is limited in magnitude, frequency, and duration, meaning it is not likely to have a significant impact on the human environment. APHIS has conducted many EAs on the operational use of functionally similar methods, and those methods have had no significant impact. APHIS research involving modifications of commonly used techniques is

generally intended to improve the efficacy and selectivity of these methods and would be expected to have similar or less risk of adverse impact than the methods operationally in use.

Paragraph (a)(6) would contain the current categorical exclusion for the development and production of sterile insects. We would amend this categorical exclusion to include the release of sterile insects as well. Sterile insects are bred in captivity, sterilized, and released into the environment, where they reduce the fecundity of pest populations. Environmental effects are limited due to the lack of offspring resulting from mating with the wild population. Research activities included in this category can differ from field releases discussed in proposed § 372.9 because they may be done with novel organisms and for limited duration. Research may also include novel methods for inducing sterility.

Paragraph (b) of proposed § 372.10 would expand on the categorical exclusion for the rehabilitation of APHIS facilities currently found in paragraph (c)(4) of § 372.5. Paragraph (c)(4) currently indicates that rehabilitation of existing laboratories and other APHIS facilities, functional replacement of parts and equipment, and minor additions to existing APHIS facilities are subject to categorical exclusion. We would retain this list, replacing the word “rehabilitation” with “renovation,” as the term better captures the nature of the work. We would also add categorical exclusions for the improvement, maintenance, and construction of APHIS facilities.

APHIS frequently needs to improve and maintain its facilities. Such improvement and maintenance often involves minor excavations and repairs to sidewalks and grounds. We would add these as actions that are categorically excluded, provided that they involve disturbances with negligible adverse impacts on the environment.

More extensive improvements may involve construction, expansion, or improvement of a facility when the permitting and approval process requires measures that address potential environmental effects. (For example, local or State regulations may require that certain construction techniques be used to reduce the effect of the construction on the human environment.) We are proposing to add a categorical exclusion for these more extensive improvements, if they meet the following requirements:

- The structure and proposed use are in compliance with all Federal, State, Tribal and local requirements (including Executive Order 13423, "Strengthening Federal Environmental, Energy, and Transportation Management," and other Federal Executive orders);
- The site and the scale of construction are consistent with those of existing adjacent or nearby buildings; and
- The size, purpose and location of the structure is unlikely to have significant environmental consequences or create public controversy.

A facility construction, expansion, or improvement that met these criteria would not be expected to have a significant effect on the human environment because the scope and impacts of the action would remain relatively small.

Process for Rapid Response to Emergencies

We are proposing to add a new section describing the process APHIS follows to develop environmental documentation when conducting a rapid response to an emergency. The new section reflects the CEQ guidance discussed previously. Adding new §§ 372.6 through 372.10 would require us to move the other sections in part 372. We are proposing to combine current §§ 372.6 and 372.7, which deal with early planning and consultation on NEPA matters, because they are quite short and discuss related subjects. For this reason, the last section of the current

NEPA regulations would be § 372.14 under this proposal, and we are therefore proposing to add this section as § 372.15.

APHIS frequently takes important emergency actions to prevent the spread of animal and plant pests and diseases. Without emergency action to control the spread of these pests and diseases there is a potential for significant impacts on the human environment. Many actions APHIS takes in emergencies would be categorically excluded from the need to prepare further NEPA documentation under this proposal, as these actions often fall into the categories described in proposed §§ 372.8 through 372.10. Primary examples of such actions can include quarantine, surveillance, decontamination and/or cleaning, and depopulation and disposal. However, particularly when emergency actions are not categorically excluded, it is important to minimize the potential environmental effects of those actions.

The proposed introductory section of § 372.15 would first state that, an emergency exists when immediate threats to human health and safety or immediate threats to sensitive or protected resources require that action be taken in a timeframe that does not allow sufficient time to follow the procedures for environmental review established in the CEQ regulations and these regulations.

Proposed paragraph (a) of § 372.15 would then stipulate that when the Administrator of APHIS or the Administrator's delegated Agency official responsible for environmental review determines that an emergency exists that makes it necessary to take immediate action to prevent imminent damage to public health or safety, or sensitive or protected environmental resources in a timeframe that precludes preparing and completing the usual NEPA review, which is comprised of analysis and documentation, the responsible APHIS official shall take into account

the probable environmental consequences of the emergency action and mitigate foreseeable adverse environmental effects to the extent practicable.

Proposed paragraph (b) of § 372.15 would specify that, if a proposed emergency action is normally analyzed in an EA 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 (ERAS) about completing the required NEPA compliance documentation and may authorize alternative arrangements for completing the required NEPA compliance documentation. Any alternative arrangements should focus on minimizing adverse environmental impacts of the proposed action and the emergency, and they are limited to those actions that are necessary to control the immediate aspects of the emergency. To the maximum extent practicable, these alternative arrangements should include the content, interagency coordination, and public notification and involvement that would normally be undertaken for an EA concerning the action and cannot alter the requirements of the CEQ regulations at 40 CFR 1508.9(a)(1) and (b). Any alternative arrangement also must be documented, and APHIS' Chief of ERAS will inform CEQ of the alternative arrangements at the earliest opportunity.

Proposed paragraph (c) of § 372.15 would state that APHIS shall immediately inform CEQ, through APHIS' interagency NEPA contact, when the proposed action is expected to result in significant environmental effects and there is insufficient time to allow for the preparation of an EIS. APHIS would consult CEQ and request alternative arrangements for preparing the EIS documentation in accordance with CEQ regulations.

These procedures are consistent with the CEQ regulations and guidance, and they provide clear direction to APHIS staff and the public on how APHIS will approach emergency NEPA

compliance. By explicitly providing for these emergency situations within our implementing regulations, we would ensure that timely emergency actions to counter disease and pest risks can be implemented and also ensure appropriate compliance with NEPA requirements.

Miscellaneous Changes

The name and address provided for the Agency's NEPA contact (§§ 372.3 and 372.4) are outdated. This proposal would update that information. The present agency contact for APHIS is Environmental and Risk Analysis Services, PPD, APHIS, USDA, 4700 River Road Unit 149, Riverdale, MD 20737-1238; (301) 851-3089.

Due to the proposed reorganization of APHIS' NEPA implementing regulations, paragraph (a)(3) of current § 372.9 would be found in § 372.13. This paragraph has indicated that, when changes are made to EAs and findings of no significant impact, all commenters on the EA will be mailed copies of changes directly. Due to the high volume of comments we receive that do not include mailing addresses, this provision is impractical, and we are proposing to remove it from the regulations. Consistent with the CEQ regulations at 40 CFR 1506.6(b)(1), paragraph (a)(3) of proposed § 372.13 would indicate that we would mail notice to those who provide a mailing address and who have specifically requested it on an individual action. We would continue to make all our environmental documentation publicly available on the APHIS Web site and interested parties can sign up for notifications from Regulations.gov to be e-mailed when new documents are added to the docket for a regulatory action. Interested parties can also sign up on APHIS' Stakeholder Registry⁵ to receive e-mail notification on any specific actions.

⁵ At <https://public.govdelivery.com/accounts/USDAAPHIS/subscriber/new>.

Executive Orders 12866 and 13563 and Regulatory Flexibility Act

This proposed rule has been determined to be significant for the purposes of Executive Order 12866 and, therefore, has been reviewed by the Office of Management and Budget.

We have prepared an economic analysis for this rule. The economic analysis provides a cost-benefit analysis, as required by Executive Orders 12866 and 13563, which direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. The economic analysis also examines the potential economic effects of this rule on small entities, as required by the Regulatory Flexibility Act. The economic analysis is summarized below. Copies of the full analysis are available by contacting the person listed under FOR FURTHER INFORMATION CONTACT or on the Regulations.gov Web site (see ADDRESSES above for instructions for accessing Regulations.gov).

The proposed rule would amend regulations that guide APHIS' implementation of the National Environmental Policy Act (NEPA). The amended regulations would clarify when an environmental impact statement (EIS) or an environmental analysis (EA) for an action is normally required, provide additional categories of actions for which we would prepare such documents, expand the list of actions subject to categorical exclusion from further environmental documentation and provide examples of such actions, and establish an environmental documentation process for use in regulatory emergencies.

Potentially affected entities include individuals, businesses, organizations, governmental jurisdictions, and other entities involved with APHIS in the NEPA process. A small number of

these entities may experience time and money savings. For example, in 2014 we estimate that 7 of 62 EAs would have qualified for a categorical exclusion under the amended regulations. In 2015 and 2016 respectively, we estimated that 10 of 87 and 7 of 25 EAs would have qualified for a categorical exclusion under the amended regulations. Resulting cost savings for APHIS and the affected entities are difficult to quantify and would vary by the nature of the proposed actions. It typically takes 1 week to 3 months to prepare an EA to begin clearance. It typically takes 2 to 3 years to prepare an EIS to begin clearance.

The proposal would make APHIS' NEPA process more transparent and efficient. The effects would be beneficial, but not significant. A small number of entities may experience time and money savings as a result of not having to provide the information necessary for completion of an EA. Affected small entities would include university researchers, research companies that produce veterinary biologics, research and diagnostic labs serving farmers, and producers of biocontrol agents, including Tribal entities. The proposed rule would not have a significant economic impact on a substantial number of small entities.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action would not have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 2 CFR chapter IV.)

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. If this proposed rule is adopted: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

Executive Order 13175

This proposed rule has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. Executive Order 13175 requires Federal agencies to consult and coordinate with tribes on a government-to-government basis on policies that have tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

APHIS has assessed the potential impact of this proposed rule and determined that this rule does not, to our knowledge, have tribal implications that require tribal consultation under Executive Order 13175. If a Tribe requests consultation, APHIS will work with the Office of Tribal Relations to ensure meaningful consultation is provided where changes, additions, and modifications identified herein are not expressly mandated by Congress.

National Environmental Policy Act

This proposed rule would revise the regulations that guide APHIS employees in NEPA analysis and documentation for animal and plant health management, wildlife damage

management, and animal welfare management activities. CEQ regulations do not require agencies to prepare a NEPA analysis or document before establishing agency procedures that supplement the CEQ regulations for implementing NEPA, and thus no NEPA document was prepared for this proposed rule. Agencies are required to adopt NEPA procedures that establish specific criteria for, and identification of, three categories of actions: Those that require preparation of an EIS; those that require preparation of an EA; and those that are categorically excluded from further NEPA review (40 CFR 1507.3(b)). Agency NEPA procedures assist agencies in the fulfillment of agency responsibilities under NEPA, but are not the agency's final determination of what level of NEPA analysis is required for a particular proposed action. The requirements for establishing agency NEPA procedures are set forth at 40 CFR 1505.1 and 1507.3.

Paperwork Reduction Act

This proposed rule contains no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.).

List of Subjects in 7 CFR Part 372

Administrative practice and procedure, Environmental assessment, Environmental impact statement, National Environmental Policy Act.

Accordingly, we are proposing to amend 7 CFR part 372 as follows:

PART 372—NATIONAL ENVIRONMENTAL POLICY ACT IMPLEMENTING PROCEDURES

1. The authority citation for part 372 continues to read as follows:

Authority: 42 U.S.C. 4321 et seq.; 40 CFR parts 1500-1508; 7 CFR parts 1b, 2.22, 2.80, and 371.9.

§ 372.1 [Amended]

2. Section 372.1 is amended by adding the word "(NEPA)" after the word "Act" the first time it occurs; and by removing the second and third occurrences of the words "the National Environmental Policy Act" and adding the word "NEPA" in their place.

3. Section 372.3 is revised to read as follows:

§ 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) 851-3089.

4. Section 372.4 is amended as follows:

a. In the introductory text, by adding the words "and definitions" after the word "terminology", by removing the word "(CEQ)", and by removing the word "is" and adding the word "are" in its place;

b. By revising the definitions of decisionmaker and environmental unit; and

c. By adding, in alphabetical order, definitions of Agency official responsible for environmental review and extraordinary circumstances.

The additions and revisions read as follows:

§ 372.4 Definitions.

* * * * *

Agency official responsible for environmental review. The Chief of APHIS' Environmental and Risk Analysis Services.

* * * * *

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

* * * * *

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

Extraordinary circumstances. Circumstances in which an action that is normally categorically excluded may have the potential for a significant environmental effect. When an extraordinary circumstance occurs, APHIS will determine whether those circumstances raise potential environmental issues that merit further analysis in an environmental impact statement or environmental assessment.

5. Section 372.5 is revised to read as follows:

§ 372.5 Environmental impact statements.

Actions normally requiring environmental impact statements. Actions in this category typically involve the agency, an entire program, or a substantial program component; and may include programmatic for reducing risks to animal and plant health and other human interests such as property, natural resources, and human health and safety. Actions in this category are typically characterized by their broad scope (often nationwide) or their intensity of potential effects (impacting a wide range of environmental components including, but not limited to air, water, soil, plant communities, or animal populations) or indicators (including, but not limited to dissolved oxygen content of water), whether or not affected individuals or systems can be reasonably completely identified at the time. An environmental impact statement will also

normally be prepared when an environmental assessment identifies a potential for significant impacts based upon the context and intensity factors listed by the Council on Environmental Quality (CEQ) at 40 CFR 1508.27. An EIS would also be required for an action whose scope is limited to a relatively small geographic area where there is the potential for significant impacts or there is a high degree of uncertainty concerning the potential impacts. Examples include, but are not limited to:

(a) Formulation of contingent response strategies to combat future widespread outbreaks of animal and plant diseases.

(b) Adoption of strategic or other long-range plans that prescribe a preferred course of action for future actions implementing the plan.

§ 372.6 [Redesignated]

6. Section 372.6 is redesignated as § 372.11.

§ 372.7 [Removed]

7. Section 372.7 is removed.

§§ 372.8 through 372.10 [Redesignated]

8. Sections 372.8 through 372.10 are redesignated as §§ 372.12 through 372.14, respectively.

9. New §§ 372.6 through 372.10 are added to read as follows:

§ 372.6 Environmental assessments.

Actions normally requiring environmental assessments. This category of actions is typically related to a more discrete program component but could be programmatic; however, the potential environmental impacts associated with the proposed action are not considered potentially significant at the outset of the planning process. An action in this category is

typically characterized by its limited scope (particular sites, State-wide or district-wide programs, specific or similar species, or particular activities). 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 previously been successful. Actions normally requiring an environmental assessment, but not necessarily an environmental impact statement, include:

(a) Policymakings, rulemakings, and actions 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:

(1) Development of program plans 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

(2) Implementation of program plans at the site-specific action level.

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

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

(d) Approvals and issuance of permits or licenses for proposals involving regulated genetically engineered or nonindigenous species.

(e) Programs 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.

(f) 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.

(g) Determination of nonregulated status for genetically engineered organisms.

§ 372.7 Categorical exclusions; general provisions.

(a)(1) Categorically excluded actions share many of the same characteristics—particularly in terms of the extent of program involvement, as well as the scope and effect of proposed actions—as actions that normally require environmental assessments but not necessarily environmental impact statements. APHIS considers that mitigation measures alone are not the sole key factor. Rather, there are several factors that should be included in determining whether a category of actions is categorically excluded: The extent to which mitigation measures to avoid or minimize adverse environmental impacts have been built into the actions themselves and, in some cases, standard operating procedures; Agency expertise and experience implementing the actions; and whether testing or monitoring have demonstrated there normally is no potential for significant environmental impacts. The use of a categorical exclusion requires the following three evaluation criteria be met:

(i) The action has not been segmented. Determine whether the action has not been segmented to meet the definition of a categorical exclusion. Segmentation may occur when an action is intentionally broken down into component parts in order to avoid the appearance of significance of the total action. An action can be too narrowly defined, minimizing potential impacts in an effort to avoid a higher level of NEPA documentation. The scope of an action must include the consideration of connected actions, and the effects when applying extraordinary circumstances must consider cumulative impacts.

(ii) No extraordinary circumstances exist. Determine whether the action involves any extraordinary circumstances that would require us to preclude the use of a categorical exclusion.

(iii) The action occurs in a limited area, does not permanently adversely affect the area, and is performed with well-established procedures.

(2) The Department has promulgated a listing of categorical exclusions that are applicable to all agencies within the Department unless their procedures provide otherwise. The Departmental categorical exclusions, codified at § 1b.3(a) of this title, apply to APHIS. Additional categorical exclusions specific to APHIS are provided in §§ 372.8 through 372.10.

(3) The use of a categorical exclusion does not relieve the responsible Agency official from compliance with other statutes, such as the Resource Conservation and Recovery Act, the Endangered Species Act, or the National Historic Preservation Act. Such consultations may be required to determine the applicability of the categorical exclusion screening criteria.

(4) For categorical exclusions requiring a brief presentation of conclusions reached during screening and review of extraordinary circumstances, determinations should be presented in a record of environmental consideration. This determination can be made using current information and expertise as long as the basis for the determination is included in the record of environmental consideration. Copies of appropriate interagency correspondence can be attached to the record of environmental consideration. Example conclusions that may be reached after a review of extraordinary circumstances include:

(i) The U.S. Fish and Wildlife Service concurred through informal consultation that endangered or threatened species or designated habitat are not likely to be adversely affected.

(ii) The U.S. Army Corps of Engineers determined that the action is covered by a nationwide general permit.

(iii) State and/or local natural resource agencies have been consulted to ensure compliance with applicable environmental laws and regulations for protecting and managing natural resources such as native plant and animal species.

(b) Whenever the Agency official responsible for environmental review determines that an extraordinary circumstance is present such that a normally categorically excluded action may have the potential to significantly affect the quality of the human environment, an environmental assessment or an environmental impact statement will be prepared. Specific extraordinary circumstances for individual categorically excluded actions are listed with those actions in §§ 372.8 through 372.10.

(c) General extraordinary circumstance for conventional measures. An environmental assessment or environmental impact statement will be prepared when an extraordinary circumstance is present such that a normally categorically excludable action, as identified in §§ 372.8 through 372.10, has the potential to significantly affect the quality of the human environment. General extraordinary circumstances that preclude the use of a categorical exclusion are:

(1) A reasonable likelihood of significant impact on public health or safety.

(2) A reasonable likelihood of significant environmental effects (direct, indirect, and cumulative).

(3) A reasonable likelihood of involving effects on the environment that involve risks that are highly uncertain, unique, or are scientifically controversial.

(4) A reasonable likelihood of violating any Executive Order, Federal law, or requirements imposed for the protection of the environment.

(5) A reasonable likelihood of adversely affecting environmentally sensitive resources, unless the impact has been resolved through another environmental process (e.g., the Coastal Zone Management Act, National Historic Preservation Act, Clean Water Act, etc.).

Environmentally sensitive resources include:

(i) Proposed federally listed, threatened, or endangered species or their designated critical habitats.

(ii) Properties listed or eligible for listing on the National Register of Historic Places.

(iii) Areas having special designation or recognition such as prime or unique agricultural lands; coastal zones; designated wilderness or wilderness study areas; wild and scenic rivers; National Historic Landmarks (designated by the Secretary of the Interior); floodplains; wetlands; sole source aquifers; National Wildlife Refuges; National Parks; areas of critical environmental concern; or other areas of high environmental sensitivity.

(iv) Cultural, scientific, or historic resources.

(6) A reasonable likelihood of dividing or disrupting an established community or planned development.

(7) A reasonable likelihood of causing a substantial increase in surface transportation congestion that will decrease the level of service below acceptable levels.

(8) A reasonable likelihood of adversely impacting air quality, exceeding, or violating Federal, State, local, or Tribal air quality standards under the Clean Air Act, as amended.

(9) A reasonable likelihood of adversely impacting water quality, sole source aquifers, public water supply systems or State, local, or Tribal water quality standards established under the Clean Water Act and the Safe Drinking Water Act.

(10) A reasonable likelihood of effects on the quality of the environment that are highly controversial on environmental grounds. The term “controversial” means a substantial scientific dispute exists as to the size, nature, or effect of the proposed action rather than to the existence of opposition to a proposed action, the effect of which is relatively undisputed.

(11) A reasonable likelihood of a disproportionately high and adverse effect on low income or minority populations.

(12) Limit access to or ceremonial use of Indian sacred sites on Federal lands by Indian religious practitioners, or significantly adversely affect the physical integrity of sacred sites.

(13) Unless releases are supported by a biocontrol risk analysis or expert panel recommendation that accompanies the administrative record for the categorical exclusion documentation, the proposed action has a reasonable likelihood of contributing to the introduction, continued existence, or spread of federally recognized noxious weeds or non-native invasive species known to occur in the area; or actions that may promote the introduction, growth, or expansion of the range of noxious weed species.

(14) A greater scope or size than is normal for this category of action.

(15) A reasonable likelihood of degrading already existing poor environmental conditions. Also, initiation of a degrading influence, activity, or effect in areas not already significantly modified from their natural condition.

(16) A precedent (or makes decisions in principle) for future or subsequent actions that have a reasonable likelihood of having a future significant effect.

(17) A reasonable likelihood of:

(i) Releases of petroleum, oils, and lubricants (except from a properly functioning engine or vehicle) or reportable releases of hazardous or toxic substances as specified in 40 CFR part 302, Designation, Reportable Quantities, and Notification); or

(ii) Where the proposed action requires development or amendment of a Spill Prevention, Control, or Countermeasures Plan.

§ 372.8 Categorical exclusions; conventional measures.

(a) Overview. Conventional measures include activities such as identifications; inspections; monitoring, including surveys and surveillance, that does not cause physical alteration of the environment; testing; seizures; quarantines; removals; sanitizing, cleaning and disinfection; inoculations; and animal handling and management employed by agency programs to pursue their missions and functions. Paragraphs (b) through (l) of this section explain and give examples of conventional measures. 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 pesticides, chemicals, drugs, pheromones, contraceptives, or other potentially harmful substances, materials, and target-specific devices or remedies.

(b) Identifications. Detection and identification of premises or animals, or identification of organisms, diseases, or species causing damage or harm. These range from biological or physical marking and tracking of animals, to premises identification, and/or the use of other markers such as inert particles in feed and branding. Examples include, but are not limited to:

- (1) Commodity labels;
- (2) Issuance of a specific identification number;
- (3) Animal tags;
- (4) Radio transmitters;

(5) Microchips; and

(6) Chemicals (such as tetracycline or rhodamine B ingestion).

(c) Inspections. Inspections of articles (including fruits and vegetables) to determine if there are any plant pests present, which could involve cutting fruit for inspection; the physical inspection of animals upon entry into the United States; facility and records inspections; inspections of commodities, facilities, or fields, including paperwork and records, for approval and to assure compliance with regulations and program standards. Inspections usually follow a prescribed protocol and document findings on an inspection report form. Examples include, but are not limited to:

(1) Physical examination of plants, plant products, and animals at the port of entry.

(2) Review of containment facilities.

(3) Review of paperwork and records to assure compliance with program regulations and standards.

(d) Monitoring, including surveys, surveillance, and trapping, that does not cause physical alteration of the environment. Surveys include questionnaires to collect information and data to assess a current state or trend in activities, to determine compliance, or to determine whether a pest or disease exists in a specific area. Surveillance includes activities to collect test samples from part or all of the target population using routine collection techniques. Trapping refers to the use of capture devices that are designed to efficiently capture, restrain, or kill targeted individual animals or a group of animals (e.g., fruit flies and other insects, a raccoon, a sounder of feral swine). Capture devices used in trapping are foothold; cage; drive; quick-kill; pit (for insects and some small rodents, reptiles and amphibians); insect and sticky traps; snares and other cable restraints; nets; hands; contained animal drugs (e.g., dart guns, tranquilizer tab

devices); and insecticides. Attractants used with some types of trapping are food, odor baits or lures, pheromones, shapes, and colors. Trapping avoids risks to the viability of native nontarget species populations through use of attractants designed for specific target animals, device design and proper application, and device placement. Examples include, but are not limited to:

(1) Collection of biological or environmental samples, such as tissue, soil, or water samples and samples of fecal matter.

(2) Continual checking, by testing, trapping, or observing for the presence, absence, or prevalence of animals, pests, or disease. Information may be used to support a pest or disease status (such as pest-free or disease-free status).

(3) Surveying and monitoring for disease may or may not require the lethal removal of the animal and can often be conducted using nonlethal methods, such as collection of samples from animals killed or removed for reasons related to disease monitoring (i.e., damage management action addressed in an environmental assessment, or hunter-killed animals).

(4) Randomly selecting animals and obtaining blood samples to survey for disease, or collection of test samples.

(e) Testing. The examination or analysis of a collected sample. This activity often occurs in a laboratory, but also includes nonlethal tests that require animal-side or chute-side injection and observation in the field. Testing may require the use of specialized equipment and/or diagnostic test kits. Examples include, but are not limited to, intradermal tuberculosis testing of livestock and germplasm testing of plant material for viral infections.

(f) Seizures. Taking possession of conveyances, materials, regulated articles, plants and plant products, animals and animal products, other articles infested with a pest or determined to

be diseased or exposed to a disease, a regulated article that is mixed in a commodity, or contaminated shipping material. Examples include, but are not limited to:

(1) Confiscation of a commodity that could be a vector for a plant or animal disease or pest, or an animal or plant determined to be infested, infected, exposed, or not in compliance with APHIS regulations (such as one moved illegally or without proper paperwork).

(2) Seizure of a nonregulated commodity, seed, or propagative material containing regulated genetically engineered material.

(g) Quarantines. Actions to restrict or prohibit movement from an area, including the creation, expansion, removal, or modification of quarantines. The establishment of a quarantine can include mitigations to allow for movement of animals or commodities while preventing the spread of the animal or plant pest or disease. These mitigations are evaluated separately from the establishment of the quarantine itself. Examples of quarantines are:

(1) Quarantine of an area in which a pest or disease is known to occur to prevent movement of animals, plants, or other articles whose movement could spread the pest or disease.

(2) Changes in pest or disease status for an area or country, such as expansion or rescission of existing quarantines.

(3) Removal of quarantine restrictions when APHIS determines that it is appropriate to do so.

(h) Removals. Relocation or lethal removal of living organisms, or destruction of materials. Examples include, but are not limited to:

(1) Removal of animals in accordance with permits and agreements from the appropriate management agencies, or otherwise in accordance with regulations governing management of a

species, for the purpose of approved research studies, surveillance and monitoring, or disease or damage management, or due to pest concerns.

(2) Removal of animals or materials from premises.

(3) Removal of trees or shrubs and plants.

(4) Disposal or destruction of materials for which the Agency has regulatory authority due to, for example, completion of acknowledged or permitted activities, completion of regulated activities, or noncompliance and disposal of animals. This can include disposal of regulated articles (fruits, meat, regulated genetically engineered organisms, etc.) at ports of entry designated by U.S. Customs and Border Protection (CBP).¹ Approved methods of disposal range from burial, feeding to animals, composting, to co-burning for power generation.

(5) Routine disposal of carcasses using other approved methods, such as donation for human consumption, composting, chemical digestion, burial, and incineration.

(6) Depopulation of domestic livestock and captive wildlife due to the presence of an animal disease or the reasonable suspicion of the presence of an animal disease. Extraordinary circumstance: An outbreak of a foreign animal disease that would require the depopulation of a large number of animals potentially resulting in substantial or significant adverse impacts on the human environment.

(i) Sanitizing, cleaning, and disinfection. Treatment of an infested commodity, cleaning, and disinfection that occurs when a disease is found or there is an emergency disease outbreak, treatment of a regulated article, or treatment for carcass disposal. Examples include, but are not limited to:

¹ Further information on CBP-approved ports is available on the Internet at <http://www.cbp.gov/contact/ports>.

(1) Treatment of regulated articles at existing facilities, such as irradiation treatment and methyl bromide special use treatment.

(2) Treatment of a facility, container, or cargo hold at the port of entry to mitigate pest threats.

(3) Cleaning and disinfection of equipment, cages, facilities, or premises.

(4) Treatment of animal carcasses, using methods such as incineration, alkaline digestion, or rendering as a method to devitalize infectious material.

(j) Inoculations. Introduction of a pathogen or antigen into a living organism in order to invoke an immune response to treat or prevent a disease. Examples are:

(1) 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).

(2) Use of vaccinations or inoculations including new vaccines (for example, 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. Extraordinary circumstance: 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.

(k) Animal handling and management. Nonlethal methods not addressed elsewhere in this part that are used to prevent, monitor for, reduce, or stop disease, damage, or harm caused by animals. Examples include, but are not limited to:

(1) Restraining or handling livestock, poultry, or wildlife to facilitate examination or other activities.

(2) Cultural methods and basic habitat management, such as nonlethal management activities such as removal of food sources, modification of planting systems, modification of animal husbandry practices, water control devices for beaver dams, limited beaver dam removal, and pruning trees.

(3) Site-specific applications of nonlethal wildlife damage management practices, such as frightening devices, exclusion, capture and release, and capture and relocation.

(1) Recordkeeping and labeling. Requiring regulated parties to keep records demonstrating compliance with APHIS requirements or to label regulated articles to indicate compliance or set out restrictions on the movement of the article. Examples include, but are not limited to:

(1) Records documenting the results of trapping for insects.

(2) Records of the application of treatments.

(3) Labels indicating that the movement of a regulated article to certain areas within the United States is illegal.

(4) Records retained by approved livestock facilities and listed slaughtering or rendering establishments under 9 CFR part 71.

§ 372.9 Categorical exclusions; licensing, permitting, authorization, and approval.

Licensing and permitting refer to the issuance of a license, permit, or authorization to entities including individuals, manufacturers, distributors, agencies, organizations, or universities for field testing, environmental release, or importation or movement of animals; plants; animal, plant, or veterinary biological products; or any other regulated article. Authorization and approval are for an entity to participate in a program or perform an action. Examples of this category of action are:

(a) Animal health-related. (1) Approval of interstate movement or importation of animals via regulations or permits. Examples include, but are not limited to:

(i) Use of permits to control the interstate movement of restricted animals, such as issuance of an official document or a State form allowing the movement of restricted animals to a particular destination.

(ii) Use of permits for entry, such as pre-movement authorization for entry of animals into a State from the State animal health official of the State of destination.

(iii) Approval of international movements through the use of import and export health certificates and import or export movement permits.

(iv) Authorization to move animals out of the quarantine or buffer zone for cattle fever ticks by documentation (a State form) that confirms the animals have been inspected and found to be tick-free.

(2) Licensing of swine garbage feeding operations.

(3) Accreditation of private veterinarians.

(4) Approval and permitting of laboratories to conduct official tests.

(5) Approval of identification manufacturers to produce identification, tests, and identification devices.

(6) Listing of slaughter and rendering establishments for surveillance under 9 CFR 71.21.

(7) Approval of herd and premises plans that have environmental or waste management components.

(8) Approval of herd accreditation for tuberculosis or certification for brucellosis to document the herd's freedom from disease.

(9) Funding the depopulation of diseased herds, including indemnity and carcass disposal; authorization and funding of the collection and submission of tissue samples for testing.

(10) Approval of participation in the National Poultry Improvement Plan by issuance of a permanent approval number in accordance with 9 CFR 145.4.

(11) Authorization to ship and field test previously unlicensed veterinary biologics including veterinary biologics containing genetically engineered organisms (such as vector-based vaccines and nucleic-acid based vaccines).

(12) Issuance of a license or permit for previously unlicensed veterinary biologics including veterinary biologics containing genetically engineered organisms (such as vector-based vaccines and nucleic-acid based vaccines).

(13) Issuance of a license, permit, authorization, or approval for 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.

(14) Issuance of permits and approval of facilities to import, transport, introduce, or release live animals and products or byproducts thereof, or other organisms for which proven risk mitigation measures are applied and will require no substantial modification for the specific articles under consideration. This includes importation or interstate movement of meat, milk/milk products, eggs, hides, bones, animal tissue extracts, etc., which present no disease risk or for which there are proven animal disease risk mitigation measures, such as heating, acidification, or standard chemical treatment.

(b) Plant health-related.

(1) Issuance of permits for the importation or interstate movement of organisms into containment facilities, for the interstate movement of organisms between containment facilities, and continued maintenance and use of these organisms.

(2) Issuance of permits for the use of organisms biologically incapable of persisting in the permitted environment.

(3) Issuance of permits for uses outside of containment that are pure cultures of organisms and that are not strains of quarantine concern and occur or are likely to occur in a State's environment, and issuance of permits for the interstate movement of organisms that occur or are likely to occur in a State's environment.

(4) Issuance of permits or approvals for the importation of articles that are regulated due to plant health concerns, when the permit contains conditions that will mitigate any plant pest risk associated with the articles.

(5) Issuance of certificates or limited permits for the movement of regulated articles from areas quarantined due to plant pests.

(6) Issuance of permits for the importation or interstate movement of regulated noxious weeds and other regulated seeds.

(7) Issuance of permits for prohibited or restricted articles unloaded and landed for immediate transshipment or transportation and exportation.

(c) Biotechnology-related.

(1) Issuance of permits for the importation, interstate movement, or environmental releases of regulated genetically engineered organisms, provided that confinement measures (the

permit conditions or performance measures), such as isolation distances from compatible relatives, control of flowering, or physical barriers, minimize the interaction of the regulated article with the environment. Extraordinary circumstance: Uncertainty of confinement measures and the ability of such to prevent the interaction of the regulated genetically engineered organism with the environment.

(2) Extension of nonregulated status under part 340 of this chapter to organisms similar to those already deregulated.

(3) Notifications for environmental release, importation, or interstate movement of regulated genetically engineered organisms.

§ 372.10 Categorical exclusions; research and development and facilities.

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

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

(2) Evaluation of uses for chemicals not specifically listed on the product label, if they are used in a manner designed to limit potential effects to nontarget species.

(3) 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.

(4) Research using chemicals, management tools, or devices to test the efficacy of methods; new vaccinations not currently approved to test in the natural environment; the use of mechanical devices (such as noise and light deterrence); and existing vaccinations, chemicals, or devices used in a new way on an animal, pest, or disease similar to those on which they have previously been used.

(5) Research related to the development and evaluation of wildlife management tools, such as animal repellents, scare devices, fencing, and pesticides.

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

(b) Renovation, improvement, maintenance, and construction of facilities. Examples are:

(1) Renovation of existing laboratories and other APHIS facilities.

(2) Functional replacement of parts and equipment.

(3) Minor additions to existing APHIS facilities.

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

(5) Construction, expansion, or improvement of a facility if:

(i) The structure and proposed use are in compliance with all Federal, State, Tribal, and local requirements;

(ii) The site and scale of construction are consistent with those of existing adjacent or nearby buildings; and

(iii) The size, purpose and location of the structure is unlikely to have significant environmental consequences or create public controversy.

10. Newly redesignated § 372.11 is revised to read as follows:

§ 372.11 Early planning and consultation for applicants and non-APHIS entities.

Prospective applicants who anticipate the need for approval of proposed activities classified as normally requiring environmental documentation should contact, at their earliest opportunity, APHIS' program staff. APHIS program officials will help them determine the types of environmental analyses or documentation, if any, that need to be prepared and how they may inform decisions. The NEPA documents will incorporate by reference (as required by the CEQ regulations in 40 CFR 1502.21), to the fullest extent practicable, surveys and studies required by other environmental statutes.

11. Newly redesignated § 372.12 is amended as follows:

- a. By revising the section heading;
- b. In the paragraph heading for paragraph (a), by removing the words “Major planning” and replacing them with the word “Planning”;
- c. In paragraph (b), introductory text, by adding the words “and environmental assessment process” at the end of the second sentence; and
- d. By revising paragraphs (b)(2) and (b)(4).

The revisions read as follows:

§ 372.12 Planning and decision points and public involvement.

* * * * *

(b) * * *

(2) Opportunities for public involvement in the environmental assessment process will be announced in the same fashion as the opportunities for public involvement in the environmental impact statement process.

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

12. Newly redesignated § 372.13 is amended as follows:

a. In paragraph (a), introductory text, by adding the words “This determination is based on information provided in the NEPA document and available in the administrative record.” after the end of the first sentence;

b. In paragraph (a)(1), by removing the citation “§ 372.8” and adding the citation “§ 372.12” in its place; and

c. By revising paragraph (a)(3).

The revision reads as follows:

§ 372.13 Processing and use of environmental documents.

(a) * * *

(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.

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13. Newly redesignated § 372.14 is revised as follows:

§ 372.14 Supplementing environmental impact statements.

Once a decision to supplement an environmental impact statement is made, a notice of intent will be published. The administrative record kept in connection with the EIS will thereafter be reopened if the supplemental environmental impact statement is issued after the

record of decision is issued. 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 administrative record.

14. A new § 372.15 is added to read as follows:

§ 372.15 Process for rapid response to emergencies.

An emergency exists when immediate threats to human health and safety or immediate threats to sensitive or protected resources require that action be taken in a timeframe that does not allow sufficient time to follow the procedures for environmental review established in the CEQ regulations and these regulations.

(a) When the Administrator or the Administrator's delegated Agency official responsible for environmental review determines that an emergency exists that makes it necessary to take immediate action to prevent imminent damage to public health or safety, or sensitive or protected environmental resources in a timeframe that precludes preparing and completing the usual NEPA review, which is comprised of analysis and documentation, the responsible APHIS official shall take into account 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 § 372.6 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 completing the required NEPA compliance documentation and may authorize alternative arrangements for completing the required NEPA compliance documentation. Any alternative arrangements must be documented and notice of their use provided to CEQ.

(c) APHIS shall immediately inform the CEQ, through APHIS' interagency NEPA contact, when the proposed action is expected to result in significant environmental effects and there is insufficient time to allow for the preparation of an EIS. APHIS will consult 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.

Done in Washington, DC, this 14th day of July 2016.

Edward Avalos,

Under Secretary, Marketing and Regulatory Programs.