Rules and Regulations

Federal Register
Vol. 83, No. 101
Thursday, May 24, 2018

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: Final rule.

SUMMARY: We are amending the regulations that set out our National Environmental Policy Act implementing procedures. The amendments include clarifying the categories of actions for which we would normally complete an environmental impact statement or an environmental assessment for an action, as well as updating examples of categorically excluded actions and setting out an environmental documentation process that could be used in emergencies. The changes will serve to update the regulations and improve their clarity and effectiveness.

DATES: Effective June 25, 2018.

FOR FURTHER INFORMATION CONTACT: Dr. Eileen Sutker, APHIS Federal NEPA Contact, Environmental and Risk Analysis Services, PPD, APHIS, 4700 River Road, Unit 149, Riverdale, MD 20737–1238; (301) 851–3043.

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 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), provide a basic regulatory framework for 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 CEQ's NEPA implementing regulations in 40 CFR 1507.3, 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.

NEPA and the CEQ regulations require all agencies of the Federal Government to incorporate environmental considerations in their planning and decisionmaking. This may include the development of an Environmental Impact Statement (EIS), 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 the human 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.

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.

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) state 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.'' Accordingly, on July 20, 2016, we published in the **Federal Register** (81 FR 47051–47071, Docket No. APHIS–2013–0049) a proposal [1] to amend the regulations by adding several new types of actions that were not previously covered in the regulations. Accordingly, we also evaluated our regulations and identified changes that would reflect new authorities, activities, and data. The changes we proposed also clarified certain areas of the regulations.

We also proposed to establish or revise categorical exclusions and extraordinary circumstances under which those categorical exclusions would not apply and to revise the requirements generally relating to classification of various actions (*e.g.,* actions normally requiring EISs, actions normally requiring EAs but not necessarily EISs). Upon further consideration and in light of the comments we received, we decided not to finalize the proposed extraordinary circumstances and most of the proposed new program categorical exclusions. Instead, we are making minor adjustments to the language currently found in § 372.5 concerning these subjects to improve clarity and provide further examples of activities that fall

[1] To view the proposed rule and the comments we received, go to *https://www.regulations.gov/docket?D=APHIS-2013-0049.*

into a given class of action or may be subject to categorical exclusion. The proposed additions were accompanied by a reorganization of the regulations, which we are also not finalizing. The structure of the regulations will remain largely identical to that of the current regulations. We may revisit the issue of categorical exclusions, extraordinary circumstances, and classification of actions in a future rulemaking.

We solicited comments concerning our proposal for 60 days ending September 19, 2016. We received 12 comments by that date from advocacy groups, industry associations, and private citizens. They are discussed below by topic, with the exception of any comments received on those portions of the proposed rule we are not finalizing, as described above.

Comments Regarding Categorical Exclusions and Extraordinary Circumstances

The bulk of the comments we received related to changes we proposed to our categorical exclusions and their associated extraordinary circumstances exceptions. As stated above, in considering those comments, which covered a broad variety of issues in detail, we came to recognize the need to reevaluate our proposed categories and reconsider the scope and effect of those categories.

General Comments

One commenter stated that since the changes and additions may affect species protected under the Endangered Species Act of 1973 and their designated critical habitats, APHIS must conduct a programmatic consultation with the Fish and Wildlife Service (FWS) and the National Marine Fisheries Service (NMFS).

This rule is administrative in nature and does not affect any listed threatened or endangered species. We consult with FWS and/or NMFS when an analysis of listed species is necessary to arrive at an environmental effects determination. We will continue to consult on any future actions that may affect protected species.

The same commenter said that we should coordinate our efforts concerning NEPA with the existing initiative involving APHIS, the Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA) to modernize agency activities under the Coordinated Framework for the Regulation of Biotechnology.[2]

APHIS is involved in updating the Coordinated Framework for the Regulation of Biotechnology, which clarifies the relevant existing authorities and roles of the USDA, the FDA, and the EPA. On January 4, 2017, EPA, FDA, and USDA released the 2017 Draft Update to the Coordinated Framework for the Regulation of Biotechnology and accompanying National Strategy for Modernizing the Regulatory System for Biotechnology Products. The original Coordinated Framework for the Regulation of Biotechnology and the 2017 Draft Update identify which types of topics trigger NEPA analyses within each agency. The finalized update of the Coordinated Framework for the Regulation of Biotechnology will continue to align with the regulations, and may facilitate further regulations.

Another commenter characterized the proposed action as APHIS scaling back its NEPA obligations, despite ongoing disputes over the scope of APHIS' duties in this area.

Contrary to the commenter's assertion, this rule will improve transparency and clarity regarding APHIS activities under NEPA. Further, we will continue to apply an appropriate level of environmental documentation to every action.

Another commenter stated that they had included suggestions for corresponding changes to the NEPA implementing regulations discussed here as part of a comment submitted in connection with a notice of intent to prepare an EIS published in the **Federal Register** on February 5, 2016 (81 FR 6225–6229, Docket No. APHIS–2014–0054) titled ''Environmental Impact Statement; Introduction of the Products of Biotechnology.'' [3] The commenter also said that this action may need to be revised in light of any changes to the NEPA regulations made in this final rule.

Due to the nature of APHIS rulemaking, we cannot consider the content of comments submitted on other rules. The notice referenced by the commenter has yet to be finalized; however, if changes to the NEPA implementing regulations are necessary as a result of that action, we will make those changes accordingly via subsequent rulemaking.

One commenter pointed out several typographical errors in the preamble language and the regulatory text of the proposed rule. We have corrected the errors in the regulatory text. The preamble language is not repeated in this final rule.

Comments Regarding Definitions

In § 372.4, which contains definitions of various terms used in the regulations, we proposed to revise two existing definitions and add definitions for two additional terms. We are not finalizing the two proposed additional definitions. We determined that a definition for ''Agency official responsible for environmental review'' is unnecessary because the information we wished to convey can already be found in the definition for ''Environmental unit.'' We are not finalizing the definition for ''Extraordinary circumstances'' because, as stated previously, we are not finalizing the proposed revisions concerning extraordinary circumstances. The revisions we are finalizing remain consistent with the CEQ regulations.

One commenter suggested we add a definition for the term ''conventional,'' given that we proposed a change from ''routine measures'' to ''conventional measures'' throughout the regulations due to prior confusion about the meaning of ''routine.'' The commenter argued that the word ''conventional'' has as much potential to cause confusion as the word ''routine.''

Uses of the term ''conventional measures'' in place of ''routine measures'' were only found in those sections we are not finalizing in this document.

Comments Regarding Actions Normally Requiring Environmental Assessments But Not Necessarily Environmental Impact Statements

We proposed to set out a description of actions APHIS takes that normally require EAs but not necessarily EISs in § 372.6 (§ 372.5(b) in the final rule). An action in this class will typically be characterized by its limited scope (particular sites, species, or activities).

We are clarifying the way in which we assess potential environmental impacts in connection with an action normally requiring an EA but not necessarily an EIS. 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.

Proposed paragraph (d) of § 372.6 (§ 372.5(b)(4) in the final rule) indicated that approvals and issuance of licenses and permits for proposals involving regulated genetically engineered or

[2] Further information on the Coordinated Framework for the Regulation of Biotechnology may be found here: *https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/2017_coordinated_framework_update.pdf.*

[3] To view that notice and the comments we received go to *https://www.regulations.gov/docket?D=APHIS-2014-0054.*

regulated nonindigenous species would normally require an EA but not necessarily an EIS, unless they are categorically excluded. One commenter proposed that we refer to ''genetically engineered organisms'' separately from regulated nonindigenous species. Two commenters pointed out that we neglected to specifically exclude actions that are categorically excluded in the language of this section.

We agree with the first commenter's suggestion to use the word ''organisms'' and have changed the term used in that section to ''genetically engineered organisms or products.'' Reference to genetically engineered products is necessary in some parts of the regulations to adequately cover veterinary biologics products, such as genetically engineered subunit proteins, plasmid vectors, and other constructs that are not organisms. We agree with the point raised by the last two commenters and have added the requested language to the introductory paragraph of § 372.5(b).

Another commenter made a recommendation regarding the comingling threshold level for genetically engineered and conventional products. The commenter also stated that third-party field testing on crops with a high risk of comingling should occur.

As the proposal did not relate to such a threshold or such inspections, these comments are outside the scope of this rulemaking.

Proposed paragraph (e) of § 372.6 (§ 372.5(b)(5) in the final rule) indicated that activities to reduce damage or harm by a specific wildlife species or group of species (such as deer or birds), or to reduce a specific type of damage or harm (such as protection of agriculture from wildlife depredation and disease, management of rabies in wildlife, or protection of threatened or endangered species) normally require an EA but not necessarily an EIS, unless they are categorically excluded.

One commenter stated that a Federal court has determined that State-wide analysis of Wildlife Services' (WS) wolf damage management activities in the State of Washington violated NEPA due to the absence of an EIS in the case of *Cascadia Wildlands* v. *Woodruff* (151 F. Supp. 3d 1153 (W.D. Wash. 2015)). The commenter argued that such State-wide plans have significant environmental impacts and thus must appropriately be analyzed in an EIS. The commenter went on to say that State-wide or district-wide program analyses will allow WS to evade any assessments of compliance with Federal land-use plans (*e.g.,* forest plans and resource management plans) that govern management of lands on which it conducts its activities. The commenter argued that State-wide or district-wide analyses fail to consider that impacts may be concentrated in certain areas, as WS generally relies upon average numbers killed State-wide or district-wide.

We disagree with the commenter's characterization of *Cascadia Wildlands* v. *Woodruff* and with the commenter's assertion that the case sets a precedent whereby all State-wide plans require preparation of an EIS. The court did not order WS to complete an EIS for its wolf damage management activities in Washington. WS coordinates all activities with land management agencies on lands under their jurisdiction. For example, memoranda of understanding between WS and the U.S. Forest Service, and between WS and the Bureau of Land Management identify the authorities, coordination requirements, and responsibilities of each agency, ensuring that land-use plans are considered, and that potential conflicts with other land uses are identified and avoided or minimized. In addition, WS uses EAs to involve other agencies with applicable jurisdiction, including land and wildlife management agencies, inviting formal agency cooperation and or comments as appropriate. WS also includes a formal public comment period on all of its EAs to ensure that all issues and concerns are considered. As shown in the document entitled ''Proposed Amendments to National Environmental Policy Act Implementing Procedures (7 CFR part 372) Substantiating Document for Proposed Amendments,'' WS EAs have repeatedly demonstrated that its activities have not had significant impacts on the environment.[4]

Proposed paragraph (g) of § 372.6 (§ 372.5(b)(7) in the final rule) indicated that determinations of nonregulated status for genetically engineered organisms normally requires an EA but not necessarily an EIS, unless categorically excluded. One commenter suggested that we add language specifically stating that an EA would be required except in those cases where the action fits into one of the categorical exclusion categories associated with such actions.

While we are not adding language specifying that an EA would be required except in those cases where the action fits into one of the categorical exclusion categories associated with such actions in § 372.5(b)(7) as suggested by the commenter, we added language in the introductory paragraph of § 372.5(b) stipulating that all of the example actions described in § 372.5(b)(1) through (7) normally require an EA but not necessarily an EIS, unless categorically excluded.

Another commenter stated that extensions of determinations of nonregulated status for genetically engineered organisms were in violation of NEPA. The commenter argued that while such extensions are often granted to similar organisms, there may still be agronomic or geographic differences that would result in significant environmental impacts. At a minimum, the commenter said, these extensions warrant the preparation of EAs in order to better evaluate the potential environmental impacts of the genetically engineered organisms. This rule does not address whether extensions of genetically engineered organisms are in violation of NEPA. Moreover, we do not explicitly identify extensions of determinations of nonregulated status for genetically engineered organisms in the discussion of exceptions for categorically excluded actions found in § 372.5(d). If the decisionmaker determines that a categorically excluded action may have the potential to affect significantly the quality of the human environment, then an EA or an EIS will be prepared. Agronomic and geographic differences are among the factors that the decisionmaker will consider when determining whether a particular extension application will be categorically excluded or if preparation of an EA or EIS is required.

Another commenter suggested that we add licensing and permitting of commercial breeding operations regulated under the Animal Welfare Act to the list of actions normally requiring EAs but not necessarily EISs.

Commercial breeding operations are not specifically listed as one of the examples of such actions given in § 372.5(b) for EAs. APHIS intends to assess all animal welfare licensing and registration applications to determine if they are eligible for a categorical exclusion or if circumstances exist that will necessitate the preparation of an EA or EIS. We will document our conclusions.

We received a number of additional comments relating to the need for EAs or EISs in connection with the licensing of commercial breeding operations. Those comments are addressed below in a section entitled, ''Comments Regarding Commercial Breeding Operations.''

[4] Pages 26–27 of the document located at *https://www.regulations.gov/docket?D=APHIS-2013-0049.*

Comments Regarding Categorical Exclusions

Proposed § 372.8 (§ 372.5(c) in the final rule) lists various categorically excluded actions. We proposed to make changes to paragraph (a) of § 372.8 (§ 372.5(c)(1)(i) in the final rule) in order to expand the list of substances that may be used as part of a conventional measure (a term not finalized in this rule; instead we have retained the original term, ''routine 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. Previously, the list of substances referred only to chemicals, pesticides, or other potentially hazardous or harmful substances, materials, and target-specific devices or remedies.

While we are not finalizing the proposed language, we will respond to the comment because the current regulations cite the use of pesticides, chemicals, and other potentially hazardous or harmful substances. Two commenters objected to the inclusion of such elements in any categorically excluded action, saying that their use often has significant impacts, which require NEPA analysis. One commenter specifically cited the growth-promotion drugs ractopamine and monensin, which the commenter argued can leach into groundwater, and the growth-promotion drug tylosin, which has been linked to antibiotic resistance.

APHIS does not use these or other growth-promotion drugs in any programs, and there are no actions in which we would consider their usage.

The other commenter used as an example those pesticides classified as ''restricted use pesticides'' by the EPA, stating these are pesticides that EPA has determined are likely to cause ''unreasonable adverse effects on the environment'' if they are used ''without additional regulatory restrictions.'' The commenter went on to classify the EPA's oversight of restricted use pesticides as predominantly focused on acute exposure and therefore inadequate to protect against risks posed by regular low-level exposure, even though the pesticides may aggregate in the environment, causing harm via long-term, low-level exposure to humans and animals.

APHIS develops and uses methods that are proven to be effective, efficient in their performance, and safe in their execution. APHIS uses pesticides in accordance with all EPA requirements. As shown in the document entitled ''Proposed Amendments to National Environmental Policy Act Implementing Procedures (7 CFR Part 372) Substantiating Document for Proposed Amendments,'' these methods were analyzed in prior environmental reviews, risk assessments, and/or are monitored to demonstrate or determine whether their use could significantly impact the human environment. This includes a number of use patterns and any program mitigation measures (including contained facilities, field sites, and pens) for pesticides, chemicals, or other potentially hazardous or harmful agents. Many of these use patterns have long been known and studied by APHIS, and APHIS has seen no record of significant environmental impacts. Our NEPA analyses consider chemical movement, degradation, environmental impacts, exposure, and risk for all actions, including those actions subject to categorical exclusion.[5] This includes both potential acute and chronic risks. If any proposed activity meets any of the criteria listed in § 372.5(d), then an EA or EIS will be prepared.

We are finalizing a group of categorically excluded actions that concern research and development activities limited in magnitude, frequency, and scope that occur in laboratories, facilities, pens, or field sites. The location and organization of this section is taken from the current regulations; however, we are incorporating some of our proposed language in a new list of examples of such activities.

In § 372.8(j)(1) (§ 372.5(c)(2)(i)(A) in the final rule) we proposed to allow for the categorical exclusion of the 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). One commenter requested that we provide further guidance on the concept of ''discrete herds of livestock or wildlife undertaken in contained areas'' either via final rule or through issuance of a guidance document.

For clarity, we revised this language to cover only those vaccination trials that occur on groups of animals in areas designed to limit interaction with similar animals, or include other controls as needed to mitigate potential risk.

Section 372.8(j)(2) (§ 372.5(c)(2)(i)(D) in the final rule) states that an example of a categorically excluded research and development activity is the use of vaccinations or inoculations, including new vaccines (*e.g.,* vaccines with components inserted through genetic engineering technologies) 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. A commenter stated that the use of genetically engineered vaccines and other novel technologies may result in impacts that require analysis under NEPA.

In the case of genetically engineered vaccines and other novel technologies, if any the criteria in § 372.5(d) apply then an EA or EIS will be prepared. As shown in the document entitled ''Proposed Amendments to National Environmental Policy Act Implementing Procedures (7 CFR Part 372) Substantiating Document for Proposed Amendments,'' we note that, based on more than 20 years of experience, APHIS' Center for Veterinary Biologics has found that the impact of new vaccines and inoculations stays within the vaccinated animal.[6]

We also proposed that activities could not be categorically excluded if a previously licensed or approved biologic has been subsequently shown to be unsafe, or if it would be used at substantially higher dosage levels or for substantially different applications or circumstances than the use for which the product was previously approved. One commenter argued that an EA should not necessarily be required in every instance where a substantially higher dose or substantially different application or use circumstance is being developed and recommended we remove that language from the regulations. The commenter said that APHIS should evaluate each situation on a case-by-case basis.

While we agree that an EA is not always required where a substantially higher dose or substantially different application or use circumstance is proposed, we are making no changes to the proposed language. We will continue to consider each case individually, as the commenter suggested. An EA or EIS would not need to be prepared if we determine that a substantially higher dose or substantially different application or use circumstance for a previously licensed or approved biologic will not impact the environmental or safety factors associated with use of that biologic.

[5] Pages 14–16 and 47 of the document located at *https://www.regulations.gov/docket?D=APHIS-2013-0049.*

[6] Pages 35–36 of the document located at *https://www.regulations.gov/docket?D=APHIS-2013-0049.*

Comments Regarding Categorical Exclusions; Licensing, Permitting, Authorization, and Approval

Proposed § 372.9 (§ 372.5(c)(3) in the final rule) contained examples of various categorically excluded actions under the heading of licensing and permitting. In the preamble to the proposed rule, we explained that licensing and permitting are administrative actions for the agency, and generally occur in support of actions that later undergo analysis in an EIS or EA. To require a separate NEPA analysis for each license or permit does not allow expedient action to serve the public, and would promote piecemeal analyses.

One commenter objected to this characterization, saying that it would be a contravention of APHIS' obligations under NEPA because any individual action within a program may have significant effects and must be subject to individualized NEPA review. The commenter also argued that it is in the public interest to undertake individualized reviews where warranted.

APHIS is not trying to evade or ignore its obligations under NEPA. The CEQ regulations at 40 CFR 1508.4 give agencies the authority to identify categorical exclusions in their NEPA implementing regulations, which is what APHIS seeks to do here. It is important to understand that, in addition to EAs and EISs, categorical exclusions are consistent with NEPA. Categorical exclusions are categories of actions, which do not individually or cumulatively have a significant effect on the human environment, and are recognized as such in the agency's implementing procedures. Use of a categorical exclusion has, and will continue to include, individualized reviews prior to issuance.

Another commenter said that we provided insufficient analysis for the determination that licensing and permitting are categorically exempt. The commenter went on to say that it is unclear whether this provision is meant to apply to licensing conducted under Animal Welfare Act (AWA; Laboratory Animal Welfare Act of 1966, as amended Public Law 89–544, 7 U.S.C. 2131–2159) licensing. The commenter argued that AWA licensing actions have enormous potential for environmental harm, and so will frequently warrant at least preparation of an EA. The commenter stated that, even if there were a categorical exclusion for commercial breeder licensing, at a minimum it should specify exceptions to that categorical exclusion. The commenter found that the proposed definition, evaluation criteria, and list of extraordinary circumstances set too high a bar for judging whether an action may have a significant environmental effect.

The regulations already provide a categorical exclusion for licensing and permitting, and identify a wide variety of routine measures that could result in authorizations and approvals. Since these categories already existed within the regulations and were effective for years, we did not include additional analysis in the proposed rule. We do not agree with the commenter's position regarding our ability to evaluate an action for significant environmental effect. On the contrary, we find that the general exceptions to categorical exclusions identified in § 372.5(d) will allow us to adequately address concerns about the potential for significant impacts to the environment pursuant to AWA licensing, because this section allows the decisionmaker to determine that a categorically excluded action may have the potential to affect ''significantly'' the quality of the ''human environment.'' For additional discussion on the rest of the commenter's points specific to licensing of commercial breeding operations, please see the section below entitled, ''Comments Regarding Commercial Breeding Operations.''

Proposed paragraph (a)(2) of § 372.10 (§ 372.5(c)(2)(i)(B) in the final rule) contained a 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. A commenter stated that categorical exclusions for evaluation of novel chemical uses cannot be employed under NEPA because their application and contact with nontarget species may result in unintended environmental, human health, or ecological impacts.

Our research and testing in this area is limited to serving Agency needs, and does not encompass broadly based or basic research. We have added the stipulation that such evaluation and use must be pursuant to applicable Federal authorizations to clarify the relatively narrow application of this categorical exclusion. Use must be limited in magnitude, frequency, and scope, and it can only occur in laboratories, facilities, pens, or field sites. We also note that this is not a new categorical exclusion, only an enhanced description of activities that did not demonstrate environmental impacts in the past.

Proposed paragraph (a)(6) (§ 372.5(c)(2)(ii) in the final rule) contained the prior categorical exclusion for the development and production of sterile insects. We are also including the release of sterile insects as well.

The same commenter argued that the development and production of sterile insects may include novel methods for inducing sterility, which would require NEPA analysis. The commenter said that the field release of genetically engineered insects may have significant human health and ecological impacts.

APHIS does not develop, approve, or release genetically engineered sterile insects. Were that to change in the future, we would consider any potential environmental impacts. Any novel methods to develop sterile insects would be subject to the criteria listed in § 372.5(d).

Comments on the Process for Rapid Response to Emergencies

We are adding a new section describing the process APHIS follows to develop environmental documentation when conducting a rapid response to an emergency. 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. One commenter encouraged APHIS to take the need to control a plant disease outbreak or other exigency into account under NEPA, including in situations where a categorical exclusion does not apply.

APHIS will take NEPA into account in the event there is a need to control a plant disease outbreak or other exigency. We recognize the need to deal quickly, effectively, and efficiently with any emergency situation that may arise. We mitigate foreseeable environmental effects to the extent practicable.

Another commenter observed that our proposed text was based on CEQ regulations, but added that there have been legal challenges to this portion of those regulations. The commenter stated that, while there has been no ruling on whether the portion of the CEQ regulations dealing with rapid response to an emergency is invalid, it was noted that allowing an emergency to encompass anything more than significant, unanticipated occurrences, such as natural disasters, as opposed to circumstances of the agency's own making, seemed at odds with NEPA as this may allow for the evasion of NEPA review. The commenter concluded that APHIS should therefore specify that an

emergency exists in instances of significant, unanticipated occurrences, such as natural disasters only, and that an emergency cannot be a result of the agency's own making.

Merely adding the concept that an emergency cannot be a result of the agency's own making does not account for the types of emergency actions APHIS may need to cope with, such as unanticipated or unforeseen impacts associated with a pest or disease outbreak. In an emergency, our primary concerns include the consequences of a delayed response. The intent of this section is to create the flexibility necessary to begin a response to the emergency, regardless of cause. This section does not allow APHIS to evade NEPA analyses; instead, it adjusts the usual timeframe and sequence for analysis of any potential impact during emergencies. The timing for NEPA compliance for all non-emergency and post-emergency actions remains unchanged.

Comments Regarding Commercial Breeding Operations

As stated previously, we received a number of comments from the Humane Society of the United States (HSUS) relating to the need for EAs or EISs in connection with the licensing of commercial breeding operations. HSUS expressed surprise that we did not mention the licensing of commercial breeding operations in the proposed rule and observed that we provided no guidance for applying NEPA standards to the licensing and regulation of these operations. They disagreed with our assessment that the approval and issuance of licenses is properly categorized as administrative, and stated that we failed to articulate what mitigation measures are in place related to the environmental damage at commercial breeding facilities, nor how any such measures would render those environmental effects insignificant. Finally, they argued that a programmatic assessment of commercial breeders, brokers, and transporters is compulsory, and the regulations should clearly convey that certain individual AWA license approvals may require an individual EA or EIS.

The AWA provides for the licensing of dealers, exhibitors, and registration of research facilities, and transporters (intermediate handlers and carriers). The associated standards provide specific requirements for regulated entities under this Act (7 CFR 371.7; 9 CFR chapter 1, parts 1 through 12 (particularly part 3, Standards)). When we propose modifications to the AWA regulations, we solicit and consider public comments to those specific provisions. The NEPA regulations are not the correct place to create or modify requirements for licensing under the authority of the AWA.

Under the AWA, the action of issuing a license consists of administrative handling of applications. In practice, this means we assess forms for completeness and schedule appropriate inspections. We inspect the facilities, and they must be in compliance prior to the issuance of a license or registration. The criteria for denial of an initial application are not discretionary (9 CFR 2.11)—all who meet the requirements are licensed or registered. Potential impacts to the environment do not occur through the act of processing an application to issue a license or registration; instead, they may occur when an individual facility is noncompliant with the standards of humane care, handling, and transportation. Regulated entities are required to comply with the standards associated with their license or registration. Based on the frequency of inspections for facilities, potential environmental impacts resulting from noncompliance are expected to be localized to a specific site, short-term in duration, and completely mitigated by the corrective actions of the facility to comply with the regulations. We carefully considered the suggestion that a programmatic assessment is necessary, and find changes to the NEPA regulations are not the correct place to address these concerns. Programmatic reviews precede proposed changes to topic-specific regulations as they occur.

HSUS said that common aerosols associated with feces and urine at puppy mills that impact air quality the most are ammonia, hydrogen sulfide, methane, and carbon dioxide. They further pointed out that dogs themselves also produce methane, a potent greenhouse gas, and these combined emissions pose a serious environmental threat. Additionally, they stated that vehicle emissions from animal transporters compound this threat and should be taken into consideration, arguing that while very little is known about the bacterial and particulate emissions of animal transport vehicles which travel across the United States, they undoubtedly emit tons of harmful gases and particulates into the air while traveling between breeder and broker or pet shop.

As stated previously, APHIS' authority under the AWA is limited to the issuance of licenses, which is an administrative act with no environmental implications. EPA, not APHIS, has authority to regulate waste materials, disposal, and emissions.

HSUS also said that decomposition of dead dogs at commercial breeding operations can contribute to soil, air, and water pollution. They stated that improper mortality management can lead to environmental contamination and claimed that dead dogs have been found scattered or improperly disposed of at a number of USDA licensed facilities.

The AWA regulations in 9 CFR 3.1(f) require facilities with dogs to properly dispose of waste and dead animals in a manner that minimizes contamination and disease risks. APHIS standards (9 CFR part 3) are established by species, and do not differ by licensee or registrant. Beyond that, State and local laws determine how dead animals are disposed of within any given jurisdiction, and APHIS works with local jurisdictions during emergencies. If a mass animal health event were to lead to high mortality levels, then APHIS would likely be involved in the disposal of those carcasses as part of a joint local, State, and Federal emergency response effort.

HSUS identified noise pollution as another environmental harm associated with large-scale commercial dog breeders. They claimed that barking dogs can reach decibel levels on par with abrasive blasting or demolition at a construction site or even an ambulance siren and recommended that noise studies, as commonly performed by many localities, should be incorporated into EAs of commercial breeding operations.

As the commenter correctly points out, localities vary in their approaches to the regulation of noise. We believe that local and State regulators are better situated to assess and regulate ambient noise standards, which are then applicable to all residents of that jurisdiction.

HSUS stated that, even if an EIS is not automatically warranted in most cases, large-scale commercial breeding operations raise enough environmental concerns that APHIS should routinely be preparing EAs prior to issuing a new license for a breeding facility.

Applicants, excepting those whose operations meet the *de minimis* standards set out by APHIS, must demonstrate compliance with the AWA and its regulations in order to receive a license. The regulations establish specifications for the humane handling, care, treatment, and transportation of the species. While it is possible the regulations may change based on public comments we receive as we consider modifying program-specific rules, this

NEPA implementing regulation is not the correct place to consider this issue. We ensure appropriate NEPA documentation is prepared for all of our proposed actions. That may take the form of a categorical exclusion, an EA, or an EIS.

Miscellaneous Changes

We are changing all references to the ''administrative record'' to references to the ''record'' because the term ''administrative record'' is not the accurate use of a legal term of art.

We are also making several minor edits to improve the clarity, focus, and brevity of the regulations overall.

Therefore, for the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule, with the changes discussed in this document.

Executive Orders 12866, 13563, 13771, and Regulatory Flexibility Act

This final 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.

This final rule is expected to be an Executive Order 13771 deregulatory action as it imposes no additional costs on affected entities and individuals, and will likely benefit those businesses and individuals regulated by APHIS that participate in the NEPA process.

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 on the *Regulations.gov* website (see footnote 1 in this document for a link to *Regulations.gov*) or by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

The rule amends the APHIS regulations that set forth the procedures for implementing NEPA. The amendments to the regulations are designed to improve the clarity and effectiveness of the procedures for implementing NEPA, such as by providing new examples for when we will complete an environmental impact statement or an environmental analysis for an action and outlining an environmental documentation process to be used in emergencies.

APHIS has determined that the rule will not have a significant economic impact on a substantial number of small entities. Some entities will experience time and money savings, but the savings will benefit only a few entities each year. The rule will also serve to clarify the regulations and make the NEPA process more transparent. These actions, although beneficial, are not expected to have a significant economic impact on affected entities. The rule imposes no additional costs on affected entities and individuals or on APHIS.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will 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 13175

This 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 impact of this rule and determined that this rule does not, to our knowledge, have Tribal implications that require tribal consultation under Executive Order 13175.

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

National Environmental Policy Act

This final rule revises 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 final 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 final rule contains no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (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 amending 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 1500–1508; 7 CFR 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) 851–3043.

■ 4. Section 372.4 is amended as follows:

■ a. In the introductory text, by adding the words ''and definitions'' after the word ''terminology'' and by removing the word ''is'' and adding the word ''are'' in its place; and

■ b. By revising the definitions of *decisionmaker* and *environmental unit.*

The revisions read as follows:

§ 372.4 Definitions.

* * * * *

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

* * * * *

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

■ 5. Section 372.5 is amended as follows:

■ a. By revising the introductory text of paragraph (b);

■ b. In paragraph (b)(1)(i), by adding the word ''and'' after the semicolon;

■ c. In paragraphs (b)(1)(ii) and (b)(3), by removing the words '', except for actions that are categorically excluded, as provided in paragraph (c) of this section'';

■ d. By revising paragraph (b)(4);

■ e. By redesignating paragraph (b)(5) as paragraph (b)(6) and adding a new paragraph (b)(5);

■ f. By revising newly redesignated paragraph (b)(6);

■ g. By adding paragraph (b)(7);

■ h. By revising paragraphs (c)(1)(ii)(B), (c)(2), and (c)(3)(i);

■ i. By redesignating paragraphs (c)(3)(ii) and (iii) as paragraphs (c)(3)(iii) and (iv), respectively;

■ j. By adding a new paragraph (c)(3)(ii);

■ k. By revising paragraph (c)(4);

■ l. By adding paragraph (c)(5);

■ m. In paragraph (d)(2), by adding the word ''or'' after the semicolon; and

■ n. By removing paragraph (d)(3) and redesignating paragraph (d)(4) as paragraph (d)(3).

The additions and revisions read as follows:

§ 372.5 Classification of actions.

* * * * *

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

* * * * *

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

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

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

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

(c) * * *

(1) * * *

(ii) * * *

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

* * * * *

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

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

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

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

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

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

(3) * * *

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

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

* * * * *

(4) *Extending deregulations for genetically engineered organisms.* Extension of nonregulated status under part 340 of this chapter to organisms similar to those already deregulated.

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

(i) Renovation of existing laboratories and other facilities.

(ii) Functional replacement of parts and equipment.

(iii) Minor additions to existing facilities.

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

* * * * *

§ 372.6 [Removed]

■ 7. Section 372.6 is removed.

§§ 372.7 through 372.10 [Redesignated as §§ 372.6 through 372.9]

■ 8. Sections 372.7 through 372.10 are redesignated as §§ 372.6 through 372.9, respectively.

■ 9. Newly redesignated § 372.6 is revised to read as follows:

§ 372.6 Early planning.

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

■ 10. Newly redesignated § 372.7 is amended by revising the section heading and paragraph (b)(4) to read as follows:

§ 372.7 Planning and decision points and public involvement.

* * * * *

(b) * * *

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

■ 11. Newly redesignated § 372.8 is amended as follows:

■ a. In paragraph (a) introductory text, by adding a sentence at the end of the paragraph;

■ b. In paragraph (a)(1), by removing the citation ''§ 372.8'' and adding the citation ''§ 372.7'' in its place; and

■ c. By revising paragraph (a)(3).

The addition and revision read as follows:

§ 372.8 Processing and use of environmental documents.

(a) * * * This determination is based on information provided in the NEPA document and available in the record.

* * * * *

(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.

* * * * *

§ 372.9 [Amended]

■ 12. Newly redesignated § 372.9 is amended by removing the second sentence and the word ''administrative'' in the last sentence.

■ 13. A new § 372.10 is added to read as follows:

§ 372.10 Process for rapid response to emergencies.

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

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

(b) If a proposed emergency action is normally analyzed in an environmental assessment as described in § 372.5 and the nature and scope of proposed emergency actions are such that there is insufficient time to prepare an EA and FONSI before commencing the proposed action, the Administrator shall consult with APHIS' Chief of Environmental and Risk Analysis Services about alternative arrangements for NEPA compliance. APHIS' Chief of Environmental and Risk Analysis Services may authorize emergency alternative arrangements for completing the required NEPA compliance documentation. Any alternative arrangements must be documented and notice of their use provided to CEQ.

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

Done in Washington, DC, this 18th day of May 2018.

Greg Ibach,

Under Secretary, Marketing and Regulatory Programs.

[FR Doc. 2018–11083 Filed 5–23–18; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Rural Utilities Service

7 CFR Part 1773

RIN 0572–AC33

Policy on Audits of RUS Borrowers and Grantees

AGENCY: Rural Utilities Service, USDA.

ACTION: Final rule with request for comment; correction; delay of effective date; extension of comment period.

SUMMARY: The Rural Utilities Service (RUS) is correcting a final rule with request for comment that appeared in the **Federal Register** on May 7, 2018, and is extending the comment period and delaying the effective date. The document amended regulations regarding its Policy on Audits to incorporate 2011 revisions to the Generally Accepted Government Auditing Standards (GAGAS) issued by the Government Accountability Office (GAO), the clarified audit standards issued by the American Institute of Certified Public Accountants (AICPA) in 2011, and Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, Subpart F, Audit Requirements, issued by the Office of Management and Budget on December 26, 2013, and adopted by USDA on December 26, 2014. The document also expanded and clarified the regulations to: Include grant recipients, amend peer review requirements, amend reporting requirements, expand the options for the electronic filing of audits, and clarify a number of existing audit requirements, and amended the title to reflect this change.

DATES:

Effective Dates: The correction is effective May 24, 2018. The effective date for the final rule published in the **Federal Register** on Monday, May 7, 2018 (83 FR 19905), is delayed from July 6, 2018, to July 23, 2018.

Applicability Date: The final rule published in the **Federal Register** on Monday, May 7, 2018 (83 FR 19905), is applicable for financial audits for