

**Animal welfare: Field study; definition,**

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Rules - Animal and Plant Health Inspection Service

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## **DEPARTMENT OF AGRICULTURE**

Animal and Plant Health Inspection Service

9 CFR Part 1

Docket No. 98-043-2

Field Study; Definition

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Final rule.

**SUMMARY:** We are amending the Animal Welfare regulations by clarifying the definition of the term field study. We will clarify that a field study cannot involve an invasive procedure, harm the animals under study, or materially alter the behavior of the animals under study. As worded prior to this final rule, the definition of field study could be interpreted to mean that a field study may include one of these situations. This action will help ensure the proper use and care of animals used in field studies.

**EFFECTIVE DATE:** March 10, 2000.

**FOR FURTHER INFORMATION CONTACT:** Dr. Jerry DePoyster, Senior Veterinary Medical Officer, Animal

Care, APHIS, 4700 River Road Unit 84, Riverdale, MD 20737-1228; (301) 734-7586.

*SUPPLEMENTARY INFORMATION:* The Animal Welfare Act (AWA) ([7 U.S.C. 2131](#) et seq.) authorizes the Secretary of Agriculture to promulgate standards and other requirements governing the humane handling, housing, care, treatment, and transportation of certain animals by dealers, research facilities, exhibitors, carriers, and intermediate handlers.

The regulations established under the Act are contained in title 9 of the Code of Federal Regulations, chapter I, subchapter A, parts 1, 2, and 3. Part 1 defines various terms used in parts 2 and 3.

As defined in Sec. 1.1 of the regulations prior to this final rule, field study meant any study that is ``conducted on free-living wild animals in their natural habitat, which does not involve an invasive procedure, and which does not harm or materially alter the behavior of the animals under study."

We have always intended that field studies not include any invasive procedures, harm the animals under study, or materially alter the behavior of the animals under study. However, we were concerned that the definition, as worded above, could be interpreted to mean that a field study could include any one of these situations.

On July 31, 1998, we published in the Federal Register (63 FR 40844-40845, Docket No. 98-043-1) a proposal to amend the definition of field study in Sec. 1.1 of the regulations by defining field study as any study conducted on free-living wild animals in their natural habitat. We also proposed to add the provision that the term field study excludes any study that involves an invasive procedure or has the potential to harm or materially alter the behavior of the animals under study. This proposed action was based on the need to ensure that studies conducted in free-living wild animals in their natural habitat are correctly classified as field studies based on the definition of field study.

We solicited comments concerning our proposal for 60 days ending September 29, 1998. We received seven comments. They were from universities; animal welfare organizations; an association representing birds; an association representing fish, reptiles, and amphibians; and an association representing zoos and aquariums. Two commenters supported the proposal as written. However, one of these commenters and the remaining commenters had concerns that are discussed below.

One commenter stated that the previous definition of field study was perfectly clear and unambiguous and did not need to be amended. In addition, two commenters stated that the proposed change in the definition of field study would exclude all projects that involve invasive procedures. One commenter requested that we delay the change of the definition. Two commenters stated that any study has the potential to harm or materially alter the behavior of the animals under study; therefore, no study could be classified as a field study.

We do not believe that the previous definition was clear to everyone. For instance, two commenters stated that the proposed change in the definition of field study would exclude all projects that involve invasive procedures. However, the previous definition of field study always excluded studies that involved invasive procedures, harmed the animals under study, or materially altered the behavior of the animals under study. In addition, in the past, some entities interpreted the definition to mean that a field study may include any one of these situations as long as it did not include all of them. In our proposed definition of field study, we clarified that a study that includes any one of the situations could not be considered a field study.

As to the use of the word potential, we agree that it is unnecessary; therefore, we are removing the word

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potential from the definition of field study in this final rule.

One commenter stated that the definition is internally inconsistent. The commenter stated that if a field study is

any study conducted on free-living wild animals in their natural habitat (emphasis added), then the second part of our definition, which excludes a subset of those studies (those that involve invasive procedures or have the potential to harm or materially alter the behavior of an animal), does not make sense.

This is a question of sentence structure, which we have addressed in this final rule by changing the word "any" in the first sentence to "an" and beginning the second sentence with "However,". We believe that this change solves the sentence structure problem.

One commenter stated that the words "harm," "invasive," and "materially alter" should be defined or else the determination of whether a study should be classified as a field study will be left to the discretion of the Institutional Animal Care and Use Committee (IACUC) at different facilities. One commenter stated that the Animal and Plant Health Inspection Service (APHIS) should provide definitions for invasive or noninvasive, and one commenter stated that APHIS should provide guidelines or regulations for defining invasive procedure and standard animal husbandry procedures. In addition, one commenter stated that APHIS should issue guidelines or a policy to state what the Agency classifies as a field study.

We do not believe that the terms "harm," "invasive," and "materially alter" need to be defined. However, we are considering the development of a policy statement that would provide examples of what APHIS considers invasive or noninvasive procedures. We do not believe that guidelines or regulations for defining standard animal husbandry procedures are necessary. Standard animal husbandry procedures are procedures that are necessary for the health and maintenance of animals on a premises.

One commenter stated that the proposed definition of field study obscures rather than clarifies the intent of field studies. This commenter stated that restriction of the term field study to exclude invasive procedures does not clarify the definition. This commenter stated that field studies have no inherent implication of invasiveness and should retain the common and professional meaning of "the study of organisms in the field," and after classification as a field study, the study should then be qualified as invasive or noninvasive.

The term field study has always excluded any study that involved an invasive procedure; therefore, we have not altered the intent of the definition. In order to be absolutely clear as to what constitutes a field study, the definition of field study had to provide the situations that would exclude a study from being considered a field study under the AWA regulations.

One commenter requested clarification that our proposal would not make changes in the administration of the AWA regulations by APHIS and IACUC's and that it would not prohibit or restrict field studies or impose additional requirements on researchers.

We only clarified the definition of field study by removing the word "and" and any ambiguity created by the word "and." We did not make substantive changes, prohibit or restrict field studies, or impose additional requirements on researchers.

One commenter stated that the composition of the members of the IACUC can vary greatly and the expertise of the membership may not represent all disciplines that are subject to review. This commenter further stated that the IACUC may not have members experienced in the activities commonly conducted in field studies or experience in performing certain procedures under field conditions. Another commenter stated that most IACUC's do not include field researchers who are able to appreciate the unique conditions of field research. One commenter stated that a growing number of investigators, institutions, and granting agencies require any research use of animals in the field or laboratory to be reviewed by their IACUC, and self-determination by the investigator does not protect him or her or the institution, nor does it provide for consistent peer-reviewed determination of invasive procedures.

Comments regarding the membership and function of IACUC's are beyond the scope of this rule; however, in

accordance with Sec. 2.31(a) of the regulations, the Chief Executive Officer of the research facility is responsible for appointing the members of the IACUC. Members of the IACUC are required to have the experience and expertise to assess the research facility's animal programs, facilities, and procedures, including the review of all proposed and ongoing research projects.

The principal investigator is responsible for determining whether a study is a field study. If the principal investigator reviews a field study protocol and has questions regarding whether a procedure is invasive or noninvasive, the investigator can consult with the IACUC of the facility. In addition, in accordance with the regulations in Sec. 2.31(c)(1), at least once every 6 months the IACUC must review the research facility's program for the humane care and use of animals by using the AWA regulations as a basis for evaluation. Therefore, if a study is misclassified as a field study, the IACUC will have the opportunity to take action to reclassify the study.

One commenter stated that there are studies that involve implantation of transponders or radiotransmitters and procedures, such as marking the animals with minor clipping or branding, that could technically be considered invasive procedures and are not conducted under sterile conditions. The commenter further stated that trauma to subjects is minimized by reducing the handling time.

An invasive procedure is typically one in which the living animal is entered by either perforation or incision in a manner that could cause more than short-lived pain or distress and may materially alter the behavior of the animal for more than a short period of time. For instance, opening the body cavity of an animal would be considered invasive and could cause the animal to materially alter its behavior until completely healed from the surgery. However, implantations of microchips and transponders may not be invasive depending on the site and method of implantation.

One commenter asked if a facility that is currently licensed as an exhibitor under the AWA would have to register as a research facility if an employee is approved to initiate a noninvasive research project in the field. The commenter stated that it was unclear when a research project is considered a regulated research project.

If the research project meets the definition of field study, the research project would not fall under the AWA regulations. However, if the research project does not meet the definition of field study (i.e., includes an invasive procedure, harms, or materially alters the behavior of the animals) the research project would need to be regulated under the AWA, and the facility would need to be registered as a research facility.

One commenter stated that he could not locate the statutory authority given to the U.S. Department of Agriculture (USDA) over animal care in the wild, whether or not the animals are involved in research. The commenter stated that the AWA assigns APHIS authority over specific warm-blooded animals on

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public display or intended for use in research facilities ([7 U.S.C. 2131](#)). The commenter added that it is not clear how USDA has authority if the noninvasive research does not involve animals or activities that are in interstate or foreign commerce or does not substantially affect such commerce or its free flow as provided in the AWA ([7 U.S.C. 2131](#)).

The purpose of defining the term field study in our regulations is to exclude from the regulations those activities that meet the definition. Thus, if a study is conducted on free-living wild animals in their natural habitat and the study does not involve an invasive procedure, does not harm the animals under study, and does not materially alter the behavior of the animals under study, then that activity is not regulated.

The AWA defines animal as any live or dead dog, cat, nonhuman primate, guinea pig, hamster, rabbit, or such other warm-blooded animal as the Secretary may determine is being used, or is intended for use, for research, testing, experimentation, or exhibition purposes, or as a pet. This definition does not exclude animals in the wild.

If a research facility conducts a study on animals in the wild that does not meet the criteria for a field study, then that activity would be regulated. The AWA defines research facility as any school (except an elementary or secondary school), institution, organization, or person that uses or intends to use live animals in research, tests, or experiments and that: (1) Purchases or transports live animals in commerce; or (2) receives funds under a grant, award, loan, or contract from a department, agency, or instrumentality of the United States for the purpose of carrying out research, tests, or experiments. \* \* \*

One commenter stated that researchers appear to be circumventing the AWA by claiming that trap tests performed on wildlife are field studies. Trapping, including the testing of traps, is not regulated by the AWA.

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 Order 12866 and Regulatory Flexibility Act**

This final rule has been reviewed under Executive Order 12866. The rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

This final rule will clarify that a field study cannot include an invasive procedure, harm the animals under study, or materially alter the behavior of the animals under study.

We have always intended that field studies not include any invasive procedures, harm the animals under study, or materially alter the behavior of the animals under study. This rule makes no substantive changes to the definition. By clarifying the definition of field study, this final rule will help ensure that studies that should be covered under the Animal Welfare regulations are covered.

The only entities that will be affected by this rule will be entities that perform studies conducted on free-living wild animals in their natural habitat. We estimate that at least 50 entities may be affected by this final rule. These entities may be considered small and large entities by Small Business Administration standards, but this final rule will only affect a small portion of the entities' activities. As we are not proposing a substantive change in the definition, the effect on these entities will not be significant.

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 7 CFR part 3015, subpart V.)

#### *Executive Order 12988*

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. It is not intended to have retroactive effect. This rule would not preempt any State and local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule. The Act does not provide administrative procedures which must be exhausted prior to a judicial challenge to the provisions of this rule.

#### *Paperwork Reduction Act*

This proposed 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 9 CFR Part 1

Animal welfare, Pets, Reporting and recordkeeping requirements, Research.

Accordingly, we are amending 9 CFR part 1 as follows:

### **PART 1--DEFINITION OF TERMS**

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

Authority: [7 U.S.C. 2131](#)-2159; [7 CFR 2.22](#), 2.80, and 371.2(g).

2. In Sec. 1.1, the definition of field study is revised to read as follows:

Sec. 1.1 Definitions.

\* \* \* \* \*

Field study means a study conducted on free-living wild animals in their natural habitat. However, this term excludes any study that involves an invasive procedure, harms, or materially alters the behavior of an animal under study. \* \* \* \* \*

Done in Washington, DC, this 3rd day of February 2000. Richard L. Dunkle, Acting Administrator, Animal and Plant Health Inspection Service.

FR Doc. 00-2922Filed2-8-00; 8:45 am

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This document cites

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- [Code of Federal Regulations - Title 7: Agriculture - 7 CFR 2.22 - Under Secretary for Marketing and Regulatory Programs.](#)
  - [US Code - Title 44: Public Printing and Documents - 44 USC 3501 - Sec. 3501. Purposes](#)
  - [U.S. Code - Title 7: Agriculture - 7 USC 2131 - Sec. 2131. Congressional statement of policy](#)
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