

DEPARTMENT OF AGRICULTURE**Animal and Plant Health Inspection Service****9 CFR Part 1**

[Docket No. 88-013]

Animal Welfare—Definition of Terms**AGENCY:** Animal and Plant Health Inspection Service, USDA.**ACTION:** Proposed rule.

SUMMARY: This is a request for supplemental comments on the narrow issue of the interrelationship between Part 1 of the Animal Welfare Act regulations and our proposal to amend Part 3 of the regulations. We are proposing to amend Part 1 of the regulations concerning animal welfare, in order to update, clarify and expand the list of definitions. These changes are intended to inform the public of the scope of the regulations and to facilitate enforcement of them. These changes, many of which are required by amendments enacted on December 23, 1985, to the Animal Welfare Act (7 U.S.C. 2131, *et seq.*), complement changes we are proposing to make to Part 2 of the regulations concerning animal welfare (Regulations) and to Part 3 of the regulations concerning animal welfare (Standards).

DATES: We will consider written comments addressing only the interrelationship of Parts 1 and 2 of the regulations with the proposed standards of Part 3, as explained in greater detail in the Supplementary Information which follows, that are postmarked or received on or before May 15, 1989.

ADDRESS: Send an original and three copies of your comments to Helene R. Wright, Chief, Regulatory Analysis and Development Staff, PPD, APHIS, USDA, Room 1000, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782. Please state that your comments refer to Docket No. 88-013. Comments received may be inspected at the APHIS Public Reading Room, Room 1141, U.S. Department of Agriculture, 14th and Independence Avenue SW., Washington, DC, 8:00 a.m. to 4:30 p.m., Monday through Friday, except holidays.

FOR FURTHER INFORMATION CONTACT: Dr. R.L. Crawford, Director, Animal Care Staff, REAC, APHIS, USDA, Room 268, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, (301) 436-7833.

SUPPLEMENTARY INFORMATION:**Background**

This document would amend and expand 9 CFR Part 1, entitled "Definition of Terms" which provides the definitions for the terms used in the regulations in 9 CFR Part 2, and the standards in 9 CFR Part 3 for the humane handling, care, treatment, and transportation of regulated animals used for research or exhibition purposes, sold as pets, or transported in commerce. The Definitions, Regulations, and Standards are established pursuant to the authority in the Animal Welfare Act, as amended (7 U.S.C. 2131, *et seq.*) (the Act). This law requires the Secretary to promulgate regulations and standards governing the humane handling, housing, care, treatment, and transportation of certain animals by dealers, research facilities, exhibitors, operators of auction sales, carriers, and intermediate handlers. The standards and regulations must include minimum requirements with respect to handling, housing, feeding, sanitation, veterinary care, and other matters specified in section 13 of the Act (7 U.S.C. 2143). Upon publication of a final rule, these definitions will provide specific meanings for the most important terms used in the regulations and standards.

In a document published in the Federal Register on March 31, 1987 (52 FR 10292-10298), we proposed to amend the Animal Welfare regulations, 9 CFR Parts 1 and 2, "Definition of Terms" and "Regulations," to comply with the 1985 amendments to the Animal Welfare Act, and to expand, clarify, and revise the current regulations.

Comments were solicited concerning both proposals for a 60-day period ending June 1, 1987. This period was twice extended and ended on August 27, 1987. We received a total of 7,857 comments: 1,438 were from the research community; 987 were from dealers and exhibitors; and 5,432 were from members of the public, including humane organizations and animal welfare societies. All of the comments that were timely received were considered. Those raising objections or suggesting changes to the proposed definitions are discussed below. Comments received after the close of the comment period have not been considered.

In response to the numerous comments received, we determined that certain changes to our proposal are necessary. These changes, discussed below, have been incorporated in this revised rule. In addition, many of the comments we received in response to our March 31, 1987 proposal to amend Part 2 suggested that certain additional

terms should be defined. We have also determined that certain terms appearing in the proposed rule to amend Part 3 require definition so that the public can understand them. We are therefore adding several definitions, as discussed below, to make the regulations in Parts 2 and 3 easier to understand, thereby increasing compliance and making them more effective.

Each definition addressed below has been given its own heading to assist the reader in locating a particular term. Comments concerning the proposed definitions as a whole are discussed first under the heading, "General."

Supplemental Request for Comments on Interrelationship of Parts 1, 2, and 3 of the Animal Welfare Regulations

We received 334 comments (309 from members of the research community and 25 from members of the general public) suggesting that we revise the proposed rules for Parts 1 and 2, "Definition of Terms" and "Regulations," and publish a second proposal in the Federal Register for public comment. We also received 445 comments (400 from members of the research community and 45 from members of the general public) suggesting that we revise the proposals for Parts 1 and 2 and publish them along with our proposal for standards for the exercise of dogs and for a physical environment to promote the psychological well-being of nonhuman primates. These specific standards are mandated by the 1985 amendments to the Act.

We have determined to respond to the comments we received addressing the proposed rules, and to publish revised rules for Parts 1 and 2 in the same issue of the Federal Register as our proposal to amend Part 3 of the regulations, titled "Standards." The revised rules reflect our consideration of the nearly 8,000 comments received, our experience in administering and enforcing the regulations, and our ongoing consultation with the U.S. Department of Health and Human Services and other interested agencies. It is our present determination that upon their adoption as final rules, the revised provisions of Parts 1 and 2 will conform with the requirements of the Animal Welfare Act, as amended.

Accordingly, we are publishing Parts 1 and 2 at this time, revised from our initial proposal, as explained in detail below, to assist the public in reviewing the proposed standards for Part 3. At the urging of many commenters, we are publishing the revised rules for Parts 1 and 2 as a proposal, for the sole purpose of soliciting comments on the narrow

issue of the interrelationship of the definitions and regulations in Parts 1 and 2 with the standards we are proposing in Part 3. The public is therefore invited to comment exclusively on this issue. We will not consider comments going beyond this issue.

General

We received 307 comments (281 from the research community, 25 from members of the general public, and 1 from an exhibitor) generally endorsing the definitions as proposed but suggesting that some require clarification or revision. We received 74 comments (72 from the research community and 2 from dealers) citing the need for reorganization of the proposed regulations as a whole (Parts 1 and 2), and for clarification in general. We have further clarified or revised those definitions as necessary, based upon the comments received.

Sixteen commenters from the research community felt generally that the definitions as proposed are too rigid and specific. We disagree. The proposed definitions must be specific to be meaningful to the persons subject to the Act and to the regulations, and to enable those persons to comply with the regulations. Except as explained below, the provisions of the initial proposed rule for Part 1 continue to be included in this revised rule based on the reasons set forth in that proposal.

Administrative Unit

The 1985 amendments to the Act require that each research facility establish an Institutional Animal Committee composed of not fewer than three members (7 U.S.C. 2143(b)(1)). Of the three members, at least one must be a doctor of veterinary medicine and at least one must not be affiliated in any way with the facility, other than as a member of the Committee. Section 13(b)(1)(C) of the Act provides that "in those cases where the Committee consists of more than three members, not more than three members shall be from the same administrative unit of such facility." (7 U.S.C. 2143(b)(1)(C).) In our March 31, 1987, proposal to amend Part 2 of the regulations, we proposed requirements in § 2.35 for the composition of the Committee. As mandated by the Act, proposed § 2.35(a)(6) provided that "[i]f the Committee consists of more than three members, not more than three members shall be from the same administrative unit of such facility; * * * This provision is included in Part 2, as revised, published elsewhere in this

issue of the Federal Register. (See companion docket No. 88-014.)

We received 465 comments (440 from the research community and 25 from members of the general public) requesting that the term "administrative unit" be defined. We are therefore including the following definition of that term:

The organizational or management unit at the departmental level of a research facility.

For universities, corporations, and other research facilities, departments such as the Department of Medicine, Department of Research and Development, the Department of Chemistry, the Department of Pharmacology, the Department of Psychology, and the Department of Zoology would each be an administrative unit for purposes of Committee membership.

Ambient temperature

Three commenters stated that the proposed definition of the term "ambient temperature" is vague. Except for the addition of the word "air" before "temperature" the proposed definition has been in the regulations since 1970. We have not learned of any problems in understanding and applying this term during the past 18 years. In the absence of any problems arising from the definition of "ambient temperature" the definition remains as initially proposed.

Animal; Dog; Cat

We proposed to define the term "animal" as follows:

any live or dead dog, cat, nonhuman primate (monkey, ape), guinea pig, hamster, rabbit, or any other warmblooded animal, which is being used, or is intended for use for research, teaching, testing, experimentation, or exhibition purposes, or as a pet. This term excludes: Birds, rats and mice bred for use in research, and horses and other farm animals, such as, but not limited to livestock or poultry, used or intended for use as food or fiber, or livestock or poultry used or intended for use for improving animal nutrition, breeding, management, or production efficiency, or for improving the quality of food or fiber. With respect to a dog, the term means all dogs including those used for hunting, security, or breeding purposes.

This proposed definition prompted numerous comments, although the only substantive change we proposed to make in the current definition was to delete the phrase "which is domesticated or raised in captivity or which normally can be found in the wild state." This qualifying phrase modifies "any other warmblooded animal" in the current definition. We received 318 comments (293 from the research community and 25 from members of the

general public) generally endorsing the proposed definition. More than 1,000 commenters (991 from the general public, 24 from the research community, and 2 dealers) stated that the definition should encompass all warmblooded animals, including rats, mice, birds, and farm animals. We received 322 comments (297 from the research community and 25 from members of the general public) stating their agreement with excluding laboratory rats and mice from the definition.

When first enacted in 1966 the Act defined the term "animal" as meaning "live dogs, cats, monkeys (nonhuman primate mammals), guinea pigs, hamsters, and rabbits." In 1970 the definition was amended to include other warm-blooded animals, and to specifically exclude horses "not used for research purposes" and other farm animals when used for agricultural purposes.

Since the Animal Welfare regulations were amended in 1972 to incorporate the 1970 amendments to the Act, the definition of "animal" has included the six kinds of animals listed above and "any other warmblooded animal, which is domesticated or raised in captivity or which normally can be found in the wild state, and is being used, or is intended for use, for research, testing, experimentation, or exhibition purposes, or as a pet." The definition of "animal" has excluded "birds, rats and mice, and horses and other farm animals, such as, but not limited to livestock or poultry, used or intended for use as food or fiber, or livestock or poultry used or intended for use for improving animal nutrition, breeding, management, or production efficiency, or for improving the quality of food or fiber."

We are not changing our definition of "animal" to include horses not used for biomedical research, and other farm animals when used for agricultural purposes, because the Act does not give us authority to include them (7 U.S.C. 2132(g)). Neither are we changing our definition of "animal" to include birds, rats and mice. We do have the authority to regulate these animals, though except for wild rats and mice, we have never covered them in our regulations. However, in response to the comments we received, we are considering developing regulations and standards for them. Development of new regulations and standards requires detailed analysis of the issues involved, followed by drafting of proposed rules. It is a time-consuming process. We do not believe it would be in the best interests of animal welfare in general if we were to delay promulgating the

regulations we have proposed. We also do not believe Congress intended that we delay promulgating regulations concerning other animals pending the possible development and drafting of regulations and standards for birds, rats and mice. Therefore, we are not changing our proposed definition of "animal" to include birds, rats and mice in this rule. If we propose regulations and standards governing birds, rats and mice, we will also propose to amend the definition of "animal" to include them. We do want to note that wild rats and mice are covered by our proposed definition, though laboratory-bred rats and mice are not. We are revising the definition of "animal" to clarify this point.

We received 303 comments (278 from the research community and 25 from members of the general public) suggesting that we delete the reference to "all warmblooded animals" in the preamble statement that "[a]ll warmblooded animals are covered by the Act," because it is misleading. Although the preamble to a proposed rule does not have the force of law, we agree that this reference could have been more precise since the Act excludes certain warmblooded animals, such as horses and farm animals, not used for research purposes.

We received 103 comments (102 from the research community and 1 from a member of the general public) stating that the definition of "animal" should not include reference to "dead" animals, and 5 comments from the research community suggesting that when the regulations are meant to include dead animals the term should be so qualified. The Act defines "animal" as both live or dead animals (7 U.S.C. 2132(g)), and accordingly the Animal Welfare regulations have defined "animal" in this manner since 1972. The word "dead" was added to the definition of "animal" as part of the 1970 amendments to the Act, due to the mistreatment of animals obtained for euthanasia and preparation as laboratory specimens. Inclusion of dead animals in the regulations is determined to be necessary based upon our experience in enforcing the regulations, to prevent abuse of these animals. We agree that many of the standards proposed in companion docket number 87-004, Part 3—"Standards," published elsewhere in this issue of the Federal Register, would not apply to dead animals, and we have added footnotes to proposed Subparts A and D in Part 3, to make clear that those standards would refer to live animals unless otherwise specified.

We received 50 comments from the research community stating that the definition of "cat" likewise should not include reference to dead cats. We disagree, since the Act defines animal as any "live or dead dog, cat, * * *" and since our experience indicates the necessity to include this protection in the regulations for the reasons explained above. No change is made to the definition of "cat" in this rule.

Thirty-two commenters from the research community stated that the definition of "dog" should not include the word "dead." For the same reasons provided above regarding animals and cats, no change is made in the definition of "dog" in the rule.

We received 2 comments from the research community stating that all rodents, including gerbils and guinea pigs, should be excluded from the regulations. Guinea pigs have been included in the Act since it was first enacted in 1966. At that time the Act covered 6 kinds of animals: Dogs, cats, guinea pigs, hamsters, rabbits, and nonhuman primates. Gerbils became a regulated species when the 1970 amendments to the Act expanded the definition of "animal" to include "such other warm-blooded animal, as the Secretary may determine is being used, or is intended for use for research, testing, * * *." We do not have the authority to remove these animals from the coverage of the regulations. No change is made to the definition of "animal" based upon these comments.

Thirty-one commenters from the research community stated that the definition of "animal" should refer to "nonhuman primates (monkeys and apes)" instead of to "monkey (nonhuman primate mammal)." We agree that use of the term "nonhuman primates" is more precise because all nonhuman primates, not just monkeys and apes, are covered by the regulations. We are revising the definition of "animal" to reflect this change. Except for this revision, the definition of "animal" remains as initially proposed.

Attending veterinarian; Licensed veterinarian

The definition of "attending veterinarian" as initially proposed would mean:

a person who has graduated from a veterinary school accredited by the American Veterinary Medical Association's Council on Education or has a certificate issued by the American Veterinary Medical Association's Education Commission for Foreign Veterinary Graduates, has received training and/or experience in the care and management of the species being attended, and who has

direct or delegated responsibility for activities involving animals at a registered or licensed facility. The veterinarian must be accredited by the U.S. Department of Agriculture in accordance with regulations issued under the Animal Welfare Act.

We received 548 comments (519 from the research community, 2 from dealers, 1 from an exhibitor, and 26 from members of the general public) stating that reference to USDA accreditation should be deleted from the definition of "attending veterinarian" and that the requirement to be accredited by USDA be clarified vis-a-vis state licensure requirements. Eleven commenters from the research community suggested that we use a term other than "accredited."

There is no requirement for state licensure in the definition. Our use of the term "accredited" was intended as a means of ensuring that attending veterinarians have training and/or experience in animal welfare, including humane handling, care, and treatment of laboratory animals, in order to provide adequate veterinary care in accordance with the Animal Welfare regulations. We agree that another term, such as "registered," should be substituted for the term, "accredited," to avoid confusion with the Accreditation of Veterinarian regulations in 9 CFR Parts 160, 161, and 162. The Department is in the process of developing standards for "accreditation" (or "registration") under the Animal Welfare regulations, for publication as a proposed rule at a later date. In the interim, we are removing the references to "accreditation" from Parts 1 and 2, as revised.

The proposed definition generated numerous comments expressing concern that otherwise qualified veterinarians would not satisfy the terms of the definition and would not be eligible to serve as attending veterinarians. We received 114 comments from the research community stating that under the proposed definition there would be an inadequate number of qualified or trained veterinarians to satisfy the demand for them. Five commenters expressed particular concern that otherwise qualified veterinarians might not be eligible to be attending veterinarians because they are graduates of foreign schools and do not have a certificate issued by the American Veterinary Medical Association's (AVMA) Education Commission for Foreign Veterinary Graduates. The definition as originally proposed would exclude graduates of European programs who can be licensed to practice in some states which do not require certification by the AVMA Education Commission for Foreign

Veterinary Graduates. These veterinarians would not be allowed to serve as attending veterinarians even within the state of licensure under the terms of the definition.

It was never our intent to disqualify otherwise qualified foreign educated veterinarians. We are revising the definition to include those veterinarians who are determined by the Administrator to have equivalent formal education. We believe that there will be an adequate supply of veterinarians satisfying the revised definition of "attending veterinarian."

Similarly, the definition of "licensed veterinarian" is changed to include those who graduated from an accredited school of veterinary medicine or who have received equivalent formal education, as determined by the Administrator, and are licensed to practice veterinary medicine in some state.

The initially proposed definition of "attending veterinarian" would require training and/or experience in the care and management of the species being attended. We received 407 comments (378 from the research community, 3 from exhibitors, and 26 from members of the general public) stating that this requirement is vague. Five dealers commented that veterinarians should not be required to have experience with the particular species being attended. We disagree since the variation among the different species of animals requires that the attending veterinarian be familiar with the different requirements to promote the animals' welfare. We also believe the terms "care and management" are commonly understood and applied in animal husbandry and are adequate to provide guidance to attending veterinarians. Accordingly, we are retaining this requirement in the revised definition.

Four commenters stated their concern that the proposed definition of "attending veterinarian" would improperly shift responsibility from the Institutional Animal Care and Use Committee (Committee) to the "Attending Veterinarian." Three commenters from the research community stated that we should substitute the word "authority" for "responsibility" in the definition.

The Committee, or IACUC, has defined areas of responsibility and authority under the Act and the regulations, and the definition of "attending veterinarian" does not shift this burden. However, to make this clear, we are incorporating the suggested wording change to alleviate any concern that the "attending veterinarian" would have

responsibilities which properly belong to the Committee. Moreover, the facility, in accordance with Part 2 of the regulations, as revised, is responsible for activities involving animals and for establishing and maintaining the Committee.

The definition of "attending veterinarian" would be as follows:

a person who has graduated from a veterinary school accredited by the American Veterinary Medical Association's Council on Education, or has a certificate issued by the American Veterinary Medical Association's Education Commission for Foreign Veterinary Graduates, or has received equivalent formal education as determined by the Administrator; has received training and/or experience in the care and management of the species being attended; and who has direct or delegated authority for activities involving animals at a registered or licensed facility.

Business hours

We received a number of comments regarding the proposed definition of "business hours" as meaning "the hours between 7 a.m. and 7 p.m., Monday through Friday, except for statutory Federal holidays, each week of the year." We received 449 comments (424 from the research community and 25 from members of the general public) stating that the proposed hours are not the normal business hours for licensees and research facilities. We received 394 comments (332 from the research community, 22 from dealers, 9 from exhibitors, and 31 from members of the general public) stating that business hours should be defined as the normal business hours of the regulated entity, and 51 commenters (18 dealers and 33 from the research community) stated that business hours should be an 8-hour period between 7 a.m. and 7 p.m. We agree that some clarification of the definition is necessary to make clear our intent that for some reasonable time during the hours from 7 a.m. to 7 p.m. daily, every facility must make its animal housing facility(ies), animal use areas, and records available for APHIS inspection without an appointment or scheduled inspection being required. The facility would not have to be open during all hours between 7 a.m. and 7 p.m., and could be open fewer than 8 hours. For example, if a facility is open from noon until 7 p.m., it must be available for inspection at all times during those hours.

Accordingly, the definition of "business hours" is revised to be "a reasonable number of hours between 7 a.m. and 7 p.m., Monday through Friday, except for statutory Federal holidays, each week of the year, during which inspections by APHIS may be made."

Under this revised definition, facilities must be available for APHIS inspection every Monday through Friday, and not just on the days they are open for business or trade, since some facilities may be part-time operations or seasonal businesses but maintain animals year-round. The proposed range of hours would help avoid problems we have encountered in the past with some facilities which seem never to be open when APHIS inspectors arrive, or which purport to be open only at "other" times.

Commerce

Two commenters from the research community stated that the proposed definition of "commerce" should be clarified. We do not believe that the definition is unclear. We believe that the changes made to the current definition to indicate that intrastate activities are considered to be in commerce for purposes of the Act, and the inclusion of trade, traffic, transportation, or other commerce with any foreign country, will aid understanding of the term. The definition of "commerce" remains as proposed.

Committee

We received a number of comments concerning the proposed definition of "Committee." We received 311 comments (286 from the research community and 25 from members of the general public) stating that the Institutional Animal Care and Use Committee should be given the name used in the Act, that is, the Institutional Animal Committee, and 308 commenters (283 from the research community and 25 members of the general public) stated that research facilities should be given flexibility to identify the Committee by whatever name it selects. We received 121 comments from the research community stating that there is no statutory authority for requiring establishment of a Committee. This contention is incorrect. Section 13(b) of the Act authorizes the Secretary to require that each research facility establish at least one Institutional Animal Committee composed of members with sufficient ability "to assess animal care, treatment, and practices in experimental research * * *" (7 U.S.C. 2143(b)). We proposed the name "Institutional Animal Care and Use Committee" because it is descriptive of the areas of concern to the Committee, while the name "Institutional Animal Committee" is general and could lead to concern that the Committee would be involved in areas beyond the scope of the regulations. Our concern is not with the

name assigned to the Committee by a facility, but that the Committee, regardless of its name, carry out its responsibilities and duties. We proposed this name for purposes of uniformity and ease of reference. The definition of "Committee," including the name "Institutional Animal Care and Use Committee", remains as originally proposed.

Endangered species

We received one comment from the research community stating that the proposed definition of "endangered species" should be more specific than "those species defined in the Endangered Species Act (16 U.S.C. 1531, *et seq.*) and as it may be subsequently amended." Another comment from the research community stated that the definition should read any "endangered or threatened species as listed under the Endangered Species Act of 1973 as amended." The Endangered Species Act includes species which are determined to be endangered or threatened because of certain factors set forth in the statute. Accordingly, our proposed definition encompasses the definition suggested by the latter commenter. We believe it is impractical to be more specific in the definition of "endangered species," since the list of species covered by the Endangered Species Act is a changing one, with additions and deletions.

Euthanasia

We received 324 comments (299 from the research community and 25 from members of the general public) stating that the definition of "euthanasia" should not refer to "immediate" death and that unconsciousness need only be rapid and not "instantaneous." As stated in the Supplementary Information accompanying the March 31, 1987 proposed rule, we believe our proposal describes humane destruction of an animal. Deletion of the requirement that death be "immediate" and requiring instead that unconsciousness need only be rapid instead of instantaneous could result in use of less humane methods of euthanasia which in turn could result in prolonged suffering by the animals. No changes have been made in the definition.

The Supplementary Information accompanying the definition of "euthanasia" stated that the method used should be consistent with the recommendations of the AVMA's current Panel on Euthanasia. Eight commenters from the research community stated that the definition of "euthanasia" should set forth the specific AVMA recommendations on methods of euthanasia. We received 317

comments (292 from the research community and 25 from members of the general public) stating that all reference to the AVMA Panel on Euthanasia recommendations should be removed from the proposal since the AVMA Panel is an independent body, not subject to APHIS direction. We disagree with these comments for the following reasons. The definition as originally proposed would allow use of any humane method for euthanizing animals and does not refer to the AVMA Panel on Euthanasia recommendations. We believe it is appropriate to allow facilities to determine which humane method they wish to use. If there is a question as to whether a certain method would be considered humane, we will issue a written opinion, upon request. We believe that the recommendations of the AVMA's current Panel on Euthanasia would meet the requirements of the proposed definition. For that reason, we referred to the recommendations in the Supplementary Information to provide further guidelines to facilities in determining what methods will be considered humane. This reference is not part of the regulations.

Exotic animal

We received 358 comments (333 from the research community and 25 from members of the general public) stating that the definition of "exotic animal" as proposed would include nonhuman primates, hamsters, and some other rodents, and that these species should be excluded from this term. Five commenters (2 from the research community, 1 exhibitor, 1 dealer, and 1 member of the general public) stated that the proposed definition is confusing in general.

The proposal defined "exotic animal" as:

any animal not identified in the definition of "animal" provided in this Part that is native to a foreign country or of foreign origin or character, is not native to the United States, or was introduced from abroad. This term specifically includes animals such as, but not limited to, lions, tigers, leopards, elephants, camels, llamas, antelope, anteaters, kangaroos, and water buffalo. Species of foreign domestic cattle, such as, Ankole, Gayal, Yak are included in this group.

We agree that there could be some confusion as a result of the definition, since many animals commonly found in the United States or generally not considered exotic are "not native to the United States, or were introduced from abroad." In fact many species of dogs are not native to the United States. Therefore, we are clarifying the

definition to exclude those animals specifically included in the definition of "animal." We are also removing llamas from the definition of "exotic animal" in this revised rule because of the increasing numbers of llamas used on farms for breeding purposes.

Farm animal

We received 319 comments (294 from the research community and 25 from members of the general public) stating that the proposed definition of "farm animal" is confusing since it defines farm animals in terms of their use rather than their species. Seven commenters stated that our definition should be consistent with the definition of "animal" as set forth in the Animal Welfare Act. The Act excludes the following animals from the definition of "animal":

horses not used for research purposes and other farm animals, such as, but not limited to livestock or poultry, used or intended for use as food or fiber, or livestock or poultry used or intended for improving animal nutrition, breeding, management or production efficiency, or for improving the quality of food or fiber.

The proposed definition is consistent with the definition of "animal" provided in the Act, in that it is the use or intended use which excludes farm animals from the Act, not their species. We are expanding the definition to include all the uses listed in the Act, in accordance with the commenters' suggestion, to avoid confusion.

Four commenters stated that the definition should refer to "warmblooded" domestic species to be consistent with the definition of "animal." We believe that this is unnecessary since "animal," as defined in the regulations, is limited to warmblooded species and there is no need to further identify farm animals as warmblooded.

As stated above, we are including llamas in the definition of farm animals when used or intended for use as farm animals, as set forth in the Act.

Housing facility

We received 60 comments from the research community objecting to the proposed definition of "housing facility" as "any land, premises, shed, barn building, trailer, or other structure or area housing or intended to house animals." These commenters stated that "housing facility" should be renamed "animal facility" and that these facilities should be distinguished from "animal study area," "acute research study area," "chronic research study area," and "holding facility." We have

considered those comments but do not agree with them. We believe there is no reason to distinguish animal study area, acute research study areas, chronic research study areas, and holding facilities for purposes of the standards, since these areas are all included within housing facilities and are subject to inspection and compliance with the regulations regardless of their name or research purpose. Also, the term "housing facility" applies to any facility used by any person subject to the Act to house animals, and is not limited to research facilities. The regulations pertaining to housing facilities contained in Part 2—"Regulations" and the proposed rule for Part 3—"Standards", published elsewhere in this issue of the Federal Register (see companion docket nos. 88-014 and 87-004, respectively), are equally applicable to all persons subject to the Act and to all parts of housing facilities. The definition remains as originally proposed.

Hybrid cross

Fourteen commenters from the research community objected to the proposed differentiation between domestic and wild hybrid cross animals and stated that all hybrids should be considered wild animals. The general consensus within the Agency remains that hybrid cross animals should be considered to be domesticated animals. For this reason and for the reasons provided in the Supplementary Information accompanying the March 31, 1987 proposed rule, the definition of "hybrid cross" remains as initially proposed.

Impervious surface

The proposed definition of "impervious surface" includes the requirement that "[f]luids on such surfaces will bead or run off, * * *". We received 363 comments (338 from research community and 25 from members of the general public) objecting to this portion of the definition because some nonpermeable floor surfaces will not cause fluids to bead up or run off, but otherwise do meet the definition of "impervious surface." We agree that this can be the case with some impervious surfaces and are modifying this provision in the definition. Our concern is that the surfaces be those that can be readily cleaned and that they not absorb material which could contaminate the surface and cause problems with sanitization. The definition, as revised, includes surfaces on which fluid beads up and runs off and surfaces from which fluids can be removed without their being absorbed into the surface material.

Two dealers and two commenters from the research community stated that some species do not require impervious surfaces and that for some species impervious surfaces may in fact be detrimental to their well-being. We agree, and have addressed these situations in the standards provided in the proposed rule for Part 3—"Standards", published elsewhere in this issue of the Federal Register in companion docket no. 87-004. Those proposed standards require impervious surfaces in defined instances.

We received 317 comments (292 from the research community and 25 from members of the general public) stating that the requirements that impervious surfaces not retain odors is inappropriate since odors are a function of cleaning and not the surface. We disagree, since some surfaces absorb disturbing odors regardless of how well they are cleaned. This requirement remains in the definition.

Indoor housing facility

We received 352 comments (326 from the research community, 25 from members of the general public, and 1 from an exhibitor) stating that the requirement that an "indoor housing facility" must be capable of maintaining humidity levels of 30 to 70 percent is too rigid and should be deleted from the definition. We disagree, and we believe the required range of a 30 to 70 percent humidity level is a reasonable one. Most species of animals that would be housed in indoor housing facilities require humidity levels within this range for their general health and welfare. This is reflected in the standards provided in the proposed rule for Part 3—"Standards" and published elsewhere in this issue of the Federal Register in companion docket no. 87-004. We do not believe compliance with this requirement will prove burdensome. Facilities receiving NIH funds for research currently must provide assurance that they are in compliance with the requirements contained in the NIH Guide for the Care and Use of Laboratory Animals. The Guide provides humidity levels within this same range for dogs, cats, and nonhuman primates. The Guide provides a range of 40 to 70 percent for most other warmblooded animals. Moreover, since 1967, indoor housing facilities have been required under our regulations to have the capability of controlling the environment within the facility. The definition remains as originally proposed.

Inspector

In the March 31, 1987 proposal, we proposed to define the term, "Veterinary Services representative," as "any inspector or other person employed by the Department who is responsible for the performance of a function under the Act." (In accordance with a change in internal policy, the term, "Veterinary Services representative," has been replaced with "APHIS official" in the revised rule.) The term "inspector" also appears in Part 2 and 3 of the regulations (see companion docket nos. 88-014 and 87-004, respectively) but was not separately defined in the March 31, 1987 proposal. We believe it would be helpful to the public to define the term "inspector." Because an inspector is an APHIS official, the definition of each term would be the same. Accordingly, the term "inspector" is defined to mean "any person employed by the Department who is authorized to perform a function under the Act and the regulations in 9 CFR Parts 1, 2, and 3."

Major operative experiment

We received 74 comments, all from the research community, stating that the definition of "major operative experiment" should be changed from "any surgical intervention that penetrates and exposes a body cavity or that has the potential for producing a permanent disability" to any surgical intervention that both penetrates and exposes a major body cavity and/or is intended to cause physical or physiological impairment. We disagree.

It is necessary to define this term since the 1985 amendments to the Act plainly require standards providing that no animal be used in more than one major operative experiment from which it is allowed to recover, except (1) in cases of scientific necessity, (2) in cases of special circumstances as determined by the Secretary, or (3) when otherwise required by a research protocol (7 U.S.C. 2143(a)(3) (D) and (E)). There is no basis under the Act for requiring that a procedure result in an actual impairment or that it be performed with the established intent of causing physical or physiological impairment for it to be termed a "major operative experiment." The intended effect in performing a procedure cannot be relied upon to determine whether a procedure should be termed "major" or "minor" since that effect may or may not be accomplished. We consider that the potential for disability is sufficient to warrant considering the procedure to be "major." We do not regulate the intent underlying

experimentation, and intent should not enter into a definition of what is considered to be a "major operative experiment." The definition remains as originally proposed.

Mobile or traveling housing facility

Our proposal, published elsewhere in this issue of the *Federal Register* (see companion docket no. 87-004), to revise Part 3, Subparts A and D, would allow dogs, cats, and nonhuman primates to be maintained in four different types of animal housing facilities: indoor, outdoor, sheltered, and mobile or traveling housing facilities. Definitions for indoor, outdoor, and sheltered animal housing facilities were included in our March 31, 1987 proposal to revise Part 1 (see 52 FR 10292-10298). However, no definition of the term "mobile or traveling housing facility" was proposed. Therefore, we are adding a definition of the term as follows:

a transporting vehicle, such as a truck, trailer, or railway car, used to house animals while traveling for exhibition or public education purposes.

These purposes would include circuses, carnivals, traveling zoos, education exhibits, and traveling animal acts.

Non-conditioned animals

One exhibitor commented that the proposed definition of "non-conditioned animal" is vague. The current definition is "animals which have not been subjected to special care and treatment for sufficient time to stabilize and, where necessary, to improve their health to make them more suitable for research purposes." Since 1967 the definition of this term has been substantially as we proposed, except that the definition referred only to animals intended for use in research facilities. The proposed definition deletes the phrase "to make them more suitable for research purposes," making the term applicable to animals used by all persons subject to the Act and the regulations. We believe this change is necessary since it is equally applicable to animals held by dealers and exhibitors and to animals in transport. We inadvertently did not explain this change in the Supplementary Information to the proposed rule. The definition remains as proposed in the March 31, 1987 proposal.

Outdoor housing facility

The current definition of "outdoor housing facility" is "any structure or building, housing or intended to house animals, which does not meet the definition of "indoor housing facility"." In the March 31, 1987 proposal and in this rule, we added a definition for

another type of housing facility, known as a "sheltered housing facility." Accordingly, we proposed to define the term "outdoor housing facility" as a structure, land, or premise, housing or intended to house animals, which does not meet the definition of an indoor housing facility or a sheltered housing facility and in which temperatures cannot be controlled within set limits." Revising the definition became necessary because a sheltered housing facility is neither an outdoor nor an indoor housing facility. In this document, we are also adding a definition of the term, "mobile or traveling housing facility," which is another type of housing facility that may be used to house animals under the regulations. (Proposed specifications pertaining to sheltered and mobile or traveling animal housing facilities when used to house dogs, cats, and nonhuman primates appear in the proposed rule for Part 3—"Standards," companion docket no. 87-004, published elsewhere in this issue of the *Federal Register*. To avoid having to amend the definition of "outdoor housing facility" each time another type of housing facility is authorized for use under the regulations, we are revising the definition in this rule to mean "a structure, land, or premise, housing or intended to house animals, which does not meet the definition of any other type of housing facility provided in the regulations and in which temperatures cannot be controlled within set limits."

Three commenters (2 from the research community and 1 exhibitor) stated that a more stringent definition of "outdoor housing facility" is necessary. We believe that this is unnecessary and could prove to be too limiting in application. We encourage the design and development of animal facilities which provide animals with natural environments appropriate for the species of animal housed and which allow ready access to runs and similar areas for exercise and social interaction. We believe that providing a more exacting definition could discourage the construction of animal housing facilities of this type.

Painful procedure

We received 345 comments (320 from the research community and 25 from members of the general public) stating that the definition of "painful procedure" should be revised to be consistent with the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training" which appears in the U.S. Public Health Service Policy on Humane Care and Use of Laboratory

Animals ("PHS Policy"). All PHS-conducted or supported activities involving animals must comply with the PHS Policy. Principle V provides that "[p]rocedures with animals that may cause more than momentary or slight pain or distress should be performed with appropriate sedation, analgesia, or anesthesia. Surgical or other painful procedures should not be performed on unanesthetized animals paralyzed by chemical agents." We used similar language in the proposed definition of "painful procedure" and, as provided in Principle IV, we proposed using human beings as the reference point for determining whether a procedure is a "painful procedure." Principle IV states that "[u]nless the contrary is established, investigators should consider that procedures that cause pain or distress in human beings may cause pain or distress in other animals." We believe that our proposed definition is consistent with the PHS Policy and with the advice of the commenters, and that no revision is necessary. We received 142 comments from the research community stating that this approach is too anthropomorphic. We believe that using human standards of pain is necessary to properly define when a procedure is to be considered painful and to make the definition meaningful to those persons applying it. The definition remains as originally proposed.

Paralytic drug

In accordance with section 13(a)(3)(C)(iv) of the Act, (7 U.S.C. 2143(a)(3)(C)(iv)), § 2.30(e)(9) of the revised rule for Part 2 (see companion docket no. 88-014) provides that each research facility that engages in a painful practice or procedure using an animal must prohibit the use of paralytic drugs without anesthesia. Section 2.30(e)(10), as revised, would require that the research facility establish a written policy to ensure compliance with the prohibition. These provisions were originally proposed in § 2.30(e)(4) at 52 FR 10312.

We received 31 comments from the research community in response to the proposed rule stating that the term "paralytic drug" should be defined. We agree and are adding a definition of the term as follows:

a drug which causes partial or complete loss of muscle contraction and which has no anesthetic or analgesic properties, so that the animal cannot move, but is completely aware of its surroundings and can feel pain.

This definition is in accordance with the generally accepted usage of the term among professionals and professional

organizations and is consistent with the intent of the Act.

Pet animal

We received 5 comments (4 from the research community and 1 from a dealer) stating that the definition of "pet animal" should exclude exotic or wild animals. We agree and intended to exclude them by using the phrase "any animal that has commonly been kept as a pet animal" in the definition. To clarify this point further we are adding examples of common household pets to the definition, such as dogs, cats, guinea pigs, rabbits, and hamsters.

Positive physical contact

Our proposal to amend Part 3, Subpart A (see companion docket no. 87-004), would require that individually housed dogs receive positive physical contact with humans. We are adding a definition of the term "positive physical contact" as it is commonly understood by the public, that is, "petting, stroking, or other touching, which is beneficial to the well-being of the animal."

Primary enclosure

We did not receive any comments addressing the proposed definition of "primary enclosure." We are replacing the word "chain" in the rule with "tether," however, to include all like devices used to restrict an animal's radius of movement.

Principal investigator (investigator)

The revised rule for Part 2 of the regulations (see companion docket no. 88-014) would require that research facilities impose certain duties and responsibilities on the principal investigator in planning and carrying out the animal care and use procedure (ACUP) of a research project. We are adding a definition of the term "principal investigator" as "an employee of a research facility responsible for a proposal to conduct research and for the design and implementation of research involving animals." This is the meaning of the term as it is used in the research community. It is also the meaning of the term as it is used by the U.S. Public Health Service in its "Public Health Service Policy on Humane Care and Use of Laboratory Animals." The Policy provides guidelines, issued by the U.S. Public Health Service under the Health Research Extension Act of 1985, for the proper care and treatment of animals used in biomedical and behavioral research. We are adding the definition to Part 1 of the regulations so that members of the general public will share the same understanding of the term.

Protocol

We proposed to define the term "Protocol" as "an investigator's plan for the use of animals in a study of a biomedical problem." We received 409 comments (384 from the research community and 25 from members of the general public) objecting to use of the term "protocol" and to our proposal to require review and approval of protocols by a facility's Institutional Animal Care and Use Committee. We received 342 comments (317 from the research community and 25 from members of the general public) stating that the term is not defined in the Animal Welfare Act and should be deleted from the regulations altogether.

Although the term is not defined in the Act it does appear in section 13 of the Act (7 U.S.C. 2143), which mandates the imposition of certain responsibilities upon research facilities and upon their Committee for carrying out the purposes of the Act. We believe that use of the term "protocol" is therefore proper. We understand from the comments we received that use of this term may imply to some research facilities that APHIS would be involved in the evaluation of the design, outlines, guidelines, and scientific merit of proposed research. That is not our intent. Our concern is with the animal care and use portion of the research, that is, how the research will treat or affect an animal, the condition of an animal, and the circumstances under which an animal is maintained. Accordingly, to clarify our intentions and avoid any misunderstanding, the term "protocol" is changed in this revised rule to "animal care and use procedure" ("ACUP"). The definition is also clarified to include an investigator's plan for the care of animals in addition to a plan for the use of animals.

The comments we received concerning our statutory authority to require review of what is now termed the "animal care and use procedure" are addressed in companion docket number 88-014, Part 2—"Regulations," published elsewhere in this issue of the Federal Register.

Research facility

Thirty-seven commenters from the research community stated that the word "biomedical" should not appear in the definition of "research facility." In writing our proposed definition of "research facility," we tried to follow the language of the Act as closely as possible. This term appears in the Act's definition of "research facility" (7 U.S.C. 2132(e)).

Nineteen commenters from the research community stated that the definition of "research facility" should exclude government agencies responsible for protection and management of the wildlife resources of a state. Again, in writing our proposed definition of "research facility," we tried to follow the language of the Act as closely as possible, and the Act allows no specific exclusion of government agencies of the type described by the commenters.

After carefully considering these comments, we have decided to adopt the Act's definition of "research facility" and use it in our regulations. We believe this would avoid confusion and ensure that our regulations accomplish the intent of the Act. The only change we are making in the definition is to replace the term "Secretary" with the term "Administrator."

Retail pet store

In our proposed definition of "retail pet store," reference to exhibiting nonpet animals was inadvertently omitted, although it was included in the Supplementary Information. We are revising the definition of "retail pet store" from that appearing in the March 31, 1987 proposal to exclude establishments or persons exhibiting or offering to exhibit any wild or exotic or other nonpet species of warmblooded animals (except birds), such as skunks, raccoons, nonhuman primates, squirrels, ocelots, foxes, coyotes, etc., in addition to those selling or offering to sell these nonpet species. These establishments and persons would be required to obtain a license under Part 2 of the regulations.

We are also adding a fifth exclusion for retail pet stores that exhibit animals in a room that is separate from or adjacent to a retail pet store, in an outside area, or anywhere off the pet store premises. If the pet animals are taken off the premises for purposes of exhibition, such as at schools, parades, or shopping malls, or are placed in outside areas or areas adjacent to the pet store for use in a petting zoo-type exhibit, the establishment or person exhibiting the pet animals must obtain a license under Part 2 of the regulations. This exclusion would prevent exhibitors from claiming to be retail pet stores in order to avoid being licensed in accordance with Part 2 of the regulations.

We are deleting mink from the list of pet animals sold by retail pet stores in response to a comment regarding the proposed definition of "wild animal." We are doing so because of their vicious nature. Mink are not regulated animals.

however, when used or intended for use solely for food or fiber purposes.

Sanitize

We received 4 comments from the research community stating that "sanitize" should be redefined so as to require removal of dirt, debris and harmful contamination, instead of requiring removal and destruction, to the maximum degree that is practical, of any agents injurious to health. The definition of "sanitize" has been the same as we proposed since 1966. We do not believe it appropriate to delete the requirement to destroy injurious agents since elimination of these agents results in a more healthful environment for animals that may be exposed to them. The definition remains as proposed.

Sheltered housing facility

Three commenters from the general public stated that the definition of "sheltered housing facility" should be deleted as this type of facility could lead to mistreatment of the housed animals. In the proposed rule for Part 3—"Standards" (see companion docket no. 87-004 published elsewhere in this issue of the Federal Register), we have proposed specifications for this type of housing facility which include requirements for heating, cooling, ventilation, cleaning, drainage, and lighting. We believe that a sheltered housing facility which is in compliance with these proposed standards can be effectively used to house animals in a humane manner in accordance with the Act.

Wild animal

We proposed to define "wild animal" as:

any animal which is now or historically has been found in the wild, or in the wild state, within the boundaries of the United States, its territories, or possessions. This term includes, but is not limited to animals such as: Buffalo, deer, skunk, opossum, raccoon, armadillo, coyote, squirrel, fox, wolf.

One dealer and one member of the general public commented in disagreement with our proposed definition. One dealer stated that ferrets and mink should be classified as wild animals, and 9 dealers and 2 exhibitors stated that deer, llama, and buffalo should be classified as domestic animals. As explained above under "Retail pet store," we agree that mink should be considered a "wild animal" due to its vicious nature. The definition of "wild animal" will be changed to include mink. We disagree with the

comment with regard to ferrets, however, since they are considered to be easily handled and relatively nondangerous, and are now commonly bred and kept as pet animals. We also disagree with classifying deer as domestic animals. Although some individuals may be raised in captivity and would be considered tame, most deer are found in the wild. However, we do agree with the commenters with regard to buffalo. Buffalo are nearly extinct in the wild. Most now exist in game preserves, where they are displayed in natural settings. Under these circumstances they are not wild animals. Therefore, we are removing them from the definition of "wild animal." We are making no change in the definition of "wild animal" with regard to llamas because llamas were not included as wild animals in our proposed definition of the term. We also want to make it clear that wild rats and mice are included in the definition of wild animal, as distinguished from rats and mice bred in captivity for use in research, and that wild rats and mice are regulated animals under the Act.

We received no comments concerning the remaining definitions and they remain in this rule as originally proposed.

Miscellaneous

As a result of a change in internal policy, the term "Veterinary Services" is replaced with "APHIS" wherever it appears and the definition of "Veterinary Services" is not included in this revised rule. We have defined "APHIS" to mean "the Animal and Plant Health Inspection Service, United States Department of Agriculture."

In order to be consistent with this change in policy, the term "Veterinary Services representative," is replaced with "APHIS official." We proposed to define the term, "Veterinary Services representative" to mean "any inspector or other person employed by the Department who is responsible for the performance of a function under the Act." We have added a definition of the term "inspector" in this revised rule, as explained above. For this reason, the definition of "APHIS official" does not specifically refer to inspectors. We are using the word "authorized" in place of "responsible" in the definition of "APHIS official" because the Secretary of Agriculture is responsible for performance under the Act. Department employees are authorized to perform certain functions. We are also clarifying the definition by including the performance of functions under the regulations as well as under the Act,

because the regulations are promulgated under the Act. Accordingly, "APHIS official" is defined to mean "any person employed by the Department who is authorized to perform a function under the Act and the regulations in 9 CFR Parts 1, 2, and 3."

We are correcting the following typographical errors which appeared in the March 31, 1987 proposal:

(1) We are correcting two errors in the proposed definition of "Class "B" licensee (dealer)". In the first sentence the reference to "\$ 1.1(q)" has been changed to "\$ 1.1" since we are not lettering the paragraphs, and in the second sentence "at an auction sale" has been corrected to read "of an auction sale."

(2) We are similarly changing the reference to "\$ 1.1(x)" in the definition of "Class "C" licensee (exhibitor)" to "\$ 1.1" since we are not lettering the paragraphs.

(3) In the definition of "endangered species," the closing parentheses are placed after the statutory citation instead of the period.

Statutory authority for this Proposed Rule

This proposed rule is issued pursuant to the Animal Welfare Act (Act), as amended, 7 U.S.C. 2131-2157. Congress recently added significantly to the Secretary's responsibilities under the Act by amendments in the Food Security Act of 1985, Pub. L. No. 99-198, approved December 23, 1985. The declared policy of the Act is to ensure that animals intended for use in research facilities, as pets, or for exhibition purposes are provided humane care and treatment; to assure the humane treatment of animals during transportation; and to prevent the sale of stolen animals.

The Act mandates that the Secretary of Agriculture promulgate regulations and standards to govern the humane handling, care, treatment, and transportation of animals by dealers, exhibitors, research facilities, carriers, and intermediate handlers. To accomplish this, the Secretary must define certain key words used in the regulations and standards so that persons subject to the Act, regulations, and standards can comply with their requirements.

The Act itself defines some of the terms which appear in this rule. The Act also authorizes the Secretary to promulgate such rules, including additional definitions, as he deems necessary to effectuate the purposes of the Act.

Executive Order 12291

On March 31, 1987, the Department published proposed rules to amend Part 1—"Definition of Terms" and Part 2—"Regulations," of the Animal Welfare regulations (52 FR 10292, 10298) in order to implement the 1985 amendments to the Animal Welfare Act, Pub. L. 99-198, the "Food Security Act." The proposed action was reviewed pursuant to Executive Order 12291 and it was determined that it did not constitute a "major rule." We solicited comments with regard to the proposed rules, and have made modifications to those rules as explained in the "Supplementary Information." At this time, we are also publishing a proposal to revise the standards contained in 9 CFR Part 3—"Standards," published elsewhere in this issue of the Federal Register.

In revising Parts 1 and 2, and in preparing the proposed rule for Part 3, we assessed the economic effects of the regulations in accordance with the requirements of Executive Order 12291. We considered alternative approaches to carrying out our statutory mandate, many of which we adopted. A regulatory impact analysis of revised Parts 1 and 2, and the proposal for Part 3 was prepared. Based on that analysis, which included consideration of both quantifiable and nonquantifiable effects of the rules, the Administrator has determined that Parts 1 and 2 would have an impact on the economy in excess of \$100 million annually, and would constitute a "major rule."

The following requirements under Parts 1 and 2 represent some of the major costs to the regulated industries: (1) The establishment and responsibilities of the animal care and use committees; (2) aseptic surgical facilities and adequate pre- and post-procedural care; (3) increased responsibilities for attending veterinarians; (4) additional administrative responsibilities; (5) increases in license fees; and (6) identification for dogs and cats less than 16 weeks of age.

The economic impacts of these rules are discussed in more detail in a regulatory impact analysis, which is available for public inspection in Room 1141 of the South Building, U.S. Department of Agriculture between 8:00 a.m. and 4:30 p.m., Monday through Friday, except holidays (address above). Main findings of this analysis are summarized below.

SUMMARY OF REGULATORY IMPACT ANALYSIS

Costs	Benefits
Direct	Direct
Regulated industry.....	Increased public satisfaction from improved animal welfare*.
Capital expenditure:	Improved research information*.
(all parts) \$876 million.....	Productivity gains for regulated industries*.
(parts 1-2) \$142 million.....	
Annual costs:	
(all parts) \$207 million.....	
(parts 1-2) \$126 million.....	
APHIS program costs impact on federal sites* \$2 million.	
Indirect	Indirect
Opportunity costs for users of biomedical research (goods and service), pet industry, and animal exhibits*.	Market effects for suppliers of animal husbandry products*.
Increased federal financial support for biomedical community*.	Non-market effects*.
Non-market effects*.	

* Not quantified.

Compliance with more stringent federal regulations on the humane care and treatment of animals used for research, testing, teaching, exhibition, and business ventures would result in major direct and indirect effects imposed on the regulated industries and the general economy. An examination of the estimated cost impacts indicates that the amended regulations constitute a "major rule" based on annual effects in excess of \$100 million on the economy and large cost increases on regulated industries for animal uses and maintenance, in particular to the biomedical research community. However, this study could not properly assess the relative significance of these cost increases on the regulated industry or the presence of adverse effects on competition, innovation, and the ability of domestic enterprises to compete with foreign enterprises in international markets.

Regulated persons or establishments will be required to spend approximately \$876 million in capital expenditures over the next two or three years. Of this amount approximately 16 percent is attributable to Parts 1 and 2. If Parts 1 and 2 were enforced separately, regulated research facilities will be required to spend approximately \$142 million to renovate, equip, replace, or construct aseptic surgical facilities, and provide for adequate pre- and post-surgical care. Capital expenditures attributable to Part 3 include costs for renovation, equipment replacement, and new construction of animal housing

facility space. Capital expenditures to improve animal housing facilities would result from the new minimum standards for general environmental conditions, space or primary enclosure size requirements, exercise of dogs, and enrichment of nonhuman primate enclosures.

In addition to capital expenditures, total annual operating expenditures estimated at \$207 million will also be required. Approximately 60 percent of this total (\$126 million) is accounted for by Parts 1 and 2, primarily the requirements for the establishment and operations of the institutional animal care and use committees, additional responsibilities for attending veterinarians, and record-keeping requirements. Annual expenditures attributable to Part 3 would result from the need for additional personnel (animal handlers) to exercise dogs, and the daily maintenance of animal housing facilities.

An important result of this regulatory analysis is that policy decisions must consider other direct and indirect effects associated with the promulgation and enforcement of federal rules. Increased federal legislation causes important economic benefits and costs which are unevenly distributed among registrants and licensees. Direct benefits accrue to society by knowing that animals may be better cared for and treated humanely. The value of these social benefits are subject to personal preferences and concerns. Improvements in the well-being of regulated animals may also provide gains in productivity to the industry. On the other hand, increased costs of compliance will be passed from the regulated industry to consumers who purchase their goods and services. For example, the field of biomedical research and education depends heavily on the use of animals to conduct tests and experiments. Increased costs for animal uses have broader economic and health implications for all of us. Study results do not suggest that these regulations would cause establishments to abandon the use of animals since current biomedical research outlays are in excess of \$12.8 billion per year. Nonetheless, there could be important effects associated with allocating additional funds or expenditures to comply with the amended animal welfare regulations.

Regulatory Flexibility Act

As part of the regulatory impact analysis performed by the Department we have analyzed the potential impact on small entities of Parts 1 and 2, as revised, and the proposal to amend Part

3 of the Animal Welfare regulations, as required by the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Based upon our analysis, we have determined that Parts 1 and 2 of the regulations would affect all regulated small entities, primarily by increases in annual license fees and identification requirements for dogs and cats. However, these economic impacts would not be significant. It is anticipated that the largest impact on small entities would result from Part 3—"Standards", if it is implemented as proposed. 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 the provisions of Executive Order 12372, which requires intergovernmental consultation with state and local officials. (See 7 CFR 3015, Subpart V.)

Paperwork Reduction Act

In accordance with section 3507 of the Paperwork Reduction Act of 1980 (44 U.S.C. 3507), the information collection provisions that are included in this proposed rule will be submitted for approval to the Office of Management and Budget (OMB). Your written comments will be considered if you submit them to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for APHIS, Washington, DC 20503. You should submit a duplicate copy of your comments to Helene R. Wright, Chief, Regulatory Analysis and Development Staff, PPD, APHIS, USDA, Room 866, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782.

List of Subjects in 9 CFR Part 1

Animal welfare, Animal housing, Dealers, Exhibitors, Research facilities, Humane animal handling.

Accordingly, we are proposing to amend 9 CFR Part 1 as follows:

PART 1—DEFINITION OF TERMS

1. The authority citation for Part 1 would be revised to read as follows:

Authority: 7 U.S.C. 2133, 2135, 2136, 2140, 2141, 2142, 2143, 2146, 2147, 2151; 7 CFR 2.17, 2.51, and 371.2(d).

2. Section 1.1 would be revised to read as follows:

§ 1.1 Definitions

For the purposes of this subchapter, unless the context otherwise requires, the following terms shall have the meanings assigned to them in this

section. The singular form shall also signify the plural and the masculine form shall also signify the feminine. Words undefined in the following paragraphs shall have the meaning attributed to them in general usage as reflected by definitions in a standard dictionary.

"Act" means the Act of August 24, 1966 (Pub. L. 89-544), (commonly known as the Laboratory Animal Welfare Act), as amended by the Act of December 24, 1970 (Pub. L. 91-579), (the Animal Welfare Act of 1970), the Act of April 22, 1976 (Pub. L. 94-279), (the Animal Welfare Act of 1976), and the Act of December 23, 1985 (Pub. L. 99-198), (the Food Security Act of 1985), and as it may be subsequently amended.

"Administrative unit" means the organizational or management unit at the departmental level of a research facility.

"Administrator" means the Administrator of the Animal and Plant Health Inspection Service, U.S. Department of Agriculture, or any other official of the Animal and Plant Health Inspection Service to whom authority has been delegated to act in his stead.

"Ambient temperature" means the air temperature surrounding the animal.

"Animal" means any live or dead dog, cat, nonhuman primate, guinea pig, hamster, rabbit, or any other warmblooded animal, which is being used, or is intended for use for research, teaching, testing, experimentation, or exhibition purposes, or as a pet. This term excludes: Birds, rats and mice bred for use in research, and horses and other farm animals, such as, but not limited to livestock or poultry, used or intended for use as food or fiber, or livestock or poultry used or intended for use for improving animal nutrition, breeding, management, or production efficiency, or for improving the quality of food or fiber. With respect to a dog, the term means all dogs including those used for hunting, security, or breeding purposes.

"Animal act" means any performance of animals where such animals are trained to perform some behavior or action or are part of a show, performance, or exhibition.

"Animal care and use procedure" (ACUP) means an investigator's plan for the care and use of animals in a study of a biomedical problem.

"APHIS" means the Animal and Plant Health Inspection Service, United States Department of Agriculture.

"APHIS official" means any person employed by the Department who is authorized to perform a function under the Act and the regulations in 9 CFR Parts 1, 2, and 3.

"Area Veterinarian in Charge" means a veterinarian or his designee, employed by APHIS, who is assigned by the Administrator to supervise and perform the official work of APHIS in a given State or States. As used in Part 2 of this subchapter, the Area Veterinarian in Charge shall be deemed to be the person in charge of the official work of APHIS in the State in which the dealer, exhibitor, research facility, intermediate handler, carrier, or operator of an auction sale has his principal place of business.

"Attending veterinarian" means a person who has graduated from a veterinary school accredited by the American Veterinary Medical Association's Council on Education, or has a certificate issued by the American Veterinary Medical Association's Education Commission for Foreign Veterinary Graduates, or has received equivalent formal education as determined by the Administrator; has received training and/or experience in the care and management of the species being attended; and who has direct or delegated authority for activities involving animals at a facility subject to the jurisdiction of the Secretary.

"Business hours" means a reasonable number of hours between 7 a.m. and 7 p.m., Monday through Friday, except for legal Federal holidays, each week of the year, during which inspections by APHIS may be made.

"Business year" means the 12-month period during which business is conducted, and may be either on a calendar or fiscal-year basis.

"Carrier" means the operator of any airline, railroad, motor carrier, shipping line, or other enterprise which is engaged in the business of transporting any animals for hire.

"Cat" means any live or dead cat (*Felis catus*) or any cat-hybrid cross.

"Class "A" licensee" (breeder) means a person subject to the licensing requirements under Part 2 and meeting the definition of a "dealer" (§ 1.1), and whose business involving animals consists only of animals that are bred and raised on the premises in a closed or stable colony and those animals acquired for the sole purpose of maintaining or enhancing the breeding colony.

"Class "B" licensee" means a person subject to the licensing requirements under Part 2 and meeting the definition of a "dealer" (§ 1.1), and whose business includes the purchase and/or resale of any animal. This term includes brokers, and operators of an auction sale, as such individuals negotiate or arrange for the purchase, sale, or transport of

animals in commerce. Such individuals do not usually take actual physical possession or control of the animals, and do not usually hold animals in any facilities. A class "B" licensee may also exhibit animals as a minor part of the business.

"Class "C" licensee" (exhibitor) means a person subject to the licensing requirements under Part 2 and meeting the definition of an "exhibitor" (§ 1.1), and whose business involves the showing or displaying of animals to the public. A class "C" licensee may buy and sell animals as a minor part of the business in order to maintain or add to his animal collection.

"Commerce" means trade, traffic, transportation, or other commerce—

(1) Between a place in a State and any place outside of such State, including any foreign country, or between points within the same State but through any place outside thereof, or within any territory, possession, or the District of Columbia; or

(2) Which affects the commerce described in this part.

"Committee" means the Institutional Animal Care and Use Committee established under section 13(b) of the Act. It shall consist of at least three (3) members, one of whom is the attending veterinarian of the research facility and one of whom is not affiliated in any way with the facility other than as a member of the Committee. The research facility shall establish the Committee for the purpose of evaluating the care, treatment, housing, and use of animals, and for certifying compliance with the Act by the research facility.

"Dealer" means any person who, in commerce, for compensation or profit, delivers for transportation, or transports, except as a carrier, buys, or sells, or negotiates the purchase or sale of: Any dog or other animal whether alive or dead (including unborn animals, organs, limbs, blood, serum, or other parts) for research, teaching, testing, experimentation, exhibition, or for use as a pet; or any dog for hunting, security, or breeding purposes. This term does not include: A retail pet store, as defined in this section, unless such store sells any animals to a research facility, an exhibitor, or a dealer (wholesale); or any person who does not sell, or negotiate the purchase or sale of any wild or exotic animal, dog, or cat and who derives no more than \$500 gross income from the sale of animals other than wild or exotic animals, dogs, or cats, during any calendar year.

"Department" means the U.S. Department of Agriculture.

"Deputy Administrator" means the Deputy Administrator for Veterinary

Services or any other official of Veterinary Services to whom authority has been delegated to act in his stead.

"Dog" means any live or dead dog (*Canis familiaris*) or any dog-hybrid cross.

"Dwarf hamster" means any species of hamster such as the Chinese and Armenian species whose adult body size is substantially less than that attained by the Syrian or Golden species of hamsters.

"Endangered species" means those species defined in the Endangered Species Act (16 U.S.C. 1531 *et seq.*) and as it may be subsequently amended.

"Euthanasia" means the human destruction of an animal accomplished by a method which produces instantaneous unconsciousness and immediate death without evidence of pain or distress, or a method that utilizes anesthesia produced by an agent which causes painless loss of consciousness and subsequent death.

"Exhibitor" means any person (public or private) exhibiting any animals, which were purchased in commerce or the intended distribution of which affects commerce, or will affect commerce, to the public for compensation, as determined by the Secretary. This term includes carnivals, circuses, animal acts, zoos, and educational exhibits, exhibiting such animals whether operated for profit or not. This term excludes retail pet stores, horse and dog races, organizations sponsoring and all persons participating in State and county fairs, livestock shows, rodeos, field trials, coursing events, purebred dog and cat shows and any other fairs or exhibitions intended to advance agricultural arts and sciences as may be determined by the Secretary.

"Exotic Animal" means any animal not identified in the definition of "animal" provided in this part that is native to a foreign country or of foreign origin or character, is not native to the United States, or was introduced from abroad. This term specifically includes animals such as, but not limited to, lions, tigers, leopards, elephants, camels, antelope, anteaters, kangaroos, and water buffalo, and species of foreign domestic cattle, such as Ankole, Gayal, and Yak.

"Farm animal" means any domestic species of cattle, sheep, swine, goats, llamas, or horses, which are normally and have historically, been kept and raised on farms in the United States, and used or intended for use as food or fiber, or for improving animal nutrition, breeding, management, or production efficiency, or for improving the quality of food or fiber. This term also includes

animals such as rabbits, mink, and chinchilla, when they are used solely for purposes of meat or fur, and animals such as horses and llamas when used solely as work and pack animals.

"Federal agency" means an Executive agency as such term is defined in section 105 of Title 5, United States Code, and with respect to any research facility means the agency from which the research facility receives a Federal award for the conduct of research, experimentation, or testing involving the use of animals.

"Federal award" means any mechanism (including a grant, award, loan, contract, or cooperative agreement) under which Federal funds are used to support the conduct of research, experimentation, or testing, involving the use of animals. The permit system established under the authorities of the Endangered Species Act, the Marine Mammal Protection Act, and the Migratory Bird Treaty Act, are not considered to be Federal awards under the Animal Welfare Act.

"Federal research facility" means such department, agency, or instrumentality of the United States which uses live animals for research or experimentation.

"Handling" means petting, feeding, watering, cleaning, manipulating, loading, crating, shifting, transferring, immobilizing, restraining, treating, training, working and moving, or any similar activity with respect to any animal.

"Housing facility" means any land, premises, shed, barn, building, trailer, or other structure or area housing or intended to house animals.

"Hybrid cross" means an animal resulting from the crossbreeding between two different species or types of animals. Crosses between wild animal species, such as lions and tigers, are considered to be wild animals. Crosses between wild animal species and domestic animals, such as dogs and wolves or buffalo and domestic cattle, are considered to be domestic animals.

"Impervious surface" means a surface that does not permit the absorption of fluids. Such surfaces are those that can be thoroughly and repeatedly cleaned and disinfected, will not retain odors, and from which fluids bead up and run off or can be removed without their being absorbed into the surface material.

"Indoor housing facility" means any structure or building with environmental controls housing or intended to house animals and meeting the following three requirements:

(1) It must be capable of controlling the temperature within the building or structure within the limits set forth for that species of animal, of maintaining humidity levels of 30 to 70 percent and of rapidly eliminating odors from within the building; and

(2) It must be an enclosure created by the continuous connection of a roof, floor, and walls (a shed or barn set on top of the ground does not have a continuous connection between the walls and the ground unless a foundation and floor are provided); and

(3) It must have at least one door for entry and exit that can be opened and closed (any windows or openings which provide natural light must be covered with a transparent material such as glass or hard plastic).

"Intermediate handler" means any person, including a department, agency, or instrumentality of the United States or of any State or local government (other than a dealer, research facility, exhibitor, any person excluded from the definition of a dealer, research facility, or exhibitor, an operator of an auction sale, or a carrier), who is engaged in any business in which he receives custody of animals in connection with their transportation in commerce.

"Inspector" means any person employed by the Department who is authorized to perform a function under the Act and the regulations in 9 CFR Parts 1, 2, and 3.

"Isolation" in regard to marine mammals means the physical separation of animals to prevent contact and a separate, noncommon, water circulation and filtration system for the isolated animals.

"Licensed veterinarian" means a person who has graduated from an accredited school of veterinary medicine or has received equivalent formal education as determined by the Administrator, and who has a valid license to practice veterinary medicine in some State.

"Licensee" means any person licensed according to the provisions of the Act and the regulations in Part 2 of this subchapter.

"Major operative experiment" means any surgical intervention that penetrates and exposes a body cavity or that has the potential for producing a permanent disability.

"Minimum horizontal dimension" (MHD) means the diameter of a circular pool of water, or in the case of a square, rectangle, oblong, or other shape pool, the diameter of the largest circle that can be inserted within the confines of such a pool of water.

"Mobile or traveling housing facility" means a transporting vehicle such as a

truck, trailer, or railway car, used to house animals while traveling for exhibition or public education purposes.

"Nonconditioned animals" means animals which have not been subjected to special care and treatment for sufficient time to stabilize, and where necessary, to improve their health.

"Nonhuman primate" means any nonhuman member of the highest order of mammals including prosimians, monkeys, and apes.

"Operator of an auction sale" means any person who is engaged in operating an auction at which animals are purchased or sold in commerce.

"Outdoor housing facility" means any structure, building, land, or premise, housing or intended to house animals, which does not meet the definition of any other type of housing facility provided in the regulations and in which temperatures cannot be controlled within set limits.

"Painful procedure" as applied to any animal means any procedure that would reasonably be expected to cause more than slight or momentary pain or distress in a human being to which that procedure was applied, that is, pain in excess of that caused by injections or other minor procedures.

"Paralytic drug" means a drug which causes partial or complete loss of muscle contraction and which has no anesthetic or analgesic properties, so that the animal cannot move, but is completely aware of its surroundings and can feel pain.

"Person" means any individual, partnership, firm, joint stock company, corporation, association, trust, estate, or other legal entity.

"Pet animal" means any animal that has commonly been kept as a pet in family households in the United States, such as dogs, cats, guinea pigs, rabbits, and hamsters. This term excludes exotic animals and wild animals.

"Positive physical contact" means petting, stroking, or other touching which is beneficial to the well-being of the animal.

"Primary conveyance" means the main method of transportation used to convey an animal from origin to destination, such as motor vehicle, plane, ship, or train.

"Primary enclosure" means any structure or device used to restrict an animal or animals to a limited amount of space, such as a room, pen, run, cage, compartment, pool, hutch, or tether. In the case of animals restrained by a tether (e.g., dogs on chains), it includes the shelter and the area within reach of the tether.

"Principal investigator" means an employee of a research facility

responsible for a proposal to conduct research and for the design and implementation of research involving animals.

"Quorum" means a majority of the Committee members.

"Random source" means dogs and cats obtained from animal pounds or shelters, auction sales, or from any person who did not breed and raise them on his or her premises.

"Registrant" means any research facility, carrier, intermediate handler, or exhibitor not required to be licensed under section 3 of the Act, registered pursuant to the provisions of the Act and the regulations in Part 2 of this subchapter.

"Research facility" means 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: *Provided*, That the Administrator may exempt, by regulation, any such school, institution, organization, or person that does not use or intend to use live dogs or cats, except those schools, institutions, organizations, or persons, which use substantial numbers (as determined by the Administrator) of live animals the principal function of which schools, institutions, organizations, or persons, is biomedical research or testing, when in the judgment of the Administrator, any such exemption does not vitiate the purpose of the Act.

"Retail pet store" means any outlet where only the following animals are sold or offered for sale, at retail, for use as pets: Dogs, cats, rabbits, guinea pigs, hamsters, gerbils, rats, mice, gophers, chinchilla, domestic ferrets, domestic farm animals, birds, and coldblooded species. Such definition excludes—

(1) Establishments or persons who deal in dogs used for hunting, security, or breeding purposes;

(2) Establishments or persons exhibiting, selling, or offering to exhibit or sell any wild or exotic or other nonpet species or warmblooded animals (except birds), such as skunks, raccoons, nonhuman primates, squirrels, ocelots, foxes, coyotes, etc.;

(3) Any establishment or person selling warmblooded animals (except birds, and laboratory rats and mice) for research or exhibition purposes; and

(4) Any establishment wholesaling any animals (except birds, rats and mice).

(5) Any establishment exhibiting pet animals in a room that is separate from or adjacent to the retail pet store, or in an outside area, or anywhere off the retail pet store premises.

"Sanitize" means to make physically clean and to remove and destroy, to the maximum degree that is practical, agents injurious to health.

"Secretary" means the Secretary of Agriculture of the United States or his representative who shall be an employee of the Department.

"Sheltered housing facility" means a housing facility which provides the animals with shelter; protection from the elements; and protection from temperature extremes at all times. A sheltered housing facility may consist of runs or pens totally enclosed in a barn or building, or of connecting inside/outside runs or pens with the inside pens in a totally enclosed building.

"Standards" means the requirements with respect to the humane housing, exhibition, handling, care, treatment, temperature, and transportation of animals by dealers, exhibitors, research facilities, carriers, intermediate handlers, and operators of auction sales as set forth in Part 3 of this subchapter.

"State" means a State of the United States, the District of Columbia, Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, or any other territory or possession of the United States.

"Transportation device" means an interim vehicle or device, other than man, used to transport an animal between the primary conveyance and the terminal facility or in and around the terminal facility of a carrier or intermediate handler.

"Transporting vehicle" means any truck, car, trailer, airplane, ship, or railroad car used for transporting animals.

"Weaned" means that an animal has become accustomed to take solid food and has so done, without nursing, for a period of at least 5 days.

"Wild animal" means any animal which is now or historically has been found in the wild, or in the wild state, within the boundaries of the United States its territories, or possessions. This term includes, but is not limited to, animals such as: Deer, skunk, opossum, raccoon, mink, armadillo, coyote, squirrel, fox, wolf.

"Wild state" means living in its original, natural condition; not domesticated.

"Zoo" means any park, building, cage, enclosure, or other structure or premise

in which a live animal or animals are kept for public exhibition or viewing, regardless of compensation.

Done at Washington DC, this 7th day of March 1989.

James W. Glosser,
Administrator, Animal and Plant Health
Inspection Service.

[FR Doc. 89-5611 Filed 3-9-89; 2:09 pm]

BILLING CODE 3410-34-M

9 CFR Part 2

[Docket No. 88-014]

Animal Welfare Regulations

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: This is a request for supplemental comments on the narrow issue of the interrelationship between Part 2 of the Animal Welfare Act regulations and our proposal to amend Part 3 of the regulations. We are proposing to amend the Animal Welfare regulations, 9 CFR Part 2. As part of our revision, we are proposing to add some new sections and revise others. New sections would provide regulations on Institutional Animal Care and Use Committees, Attending Veterinarians, and Veterinary Care. These amendments are necessary to comply with the amendments to the Animal Welfare Act (7 U.S.C. 2131, *et seq.*) ("Act") contained in Pub. L. 99-198, "The Food Security Act of 1985," enacted December 23, 1985. We are also proposing to add new sections on Holding Facilities and Handling to improve enforcement of the Act. We are proposing to revise other portions of the regulations in content and/or format to aid the public in understanding and using the regulations for the humane care, treatment, handling, and transportation of regulated animals. Rewriting the regulations is intended to make them easier to understand, thereby increasing compliance and making them more effective.

DATE: We will consider written comments addressing only the interrelationship of Parts 1 and 2 of the regulations with the proposed standards of Part 3, as explained in greater detail in the supplementary information which follows, that are postmarked or received on or before May 15, 1989.

ADDRESS: Send an original and three copies of your comments to Helene R. Wright, Chief, Regulatory Analysis and Development Staff, PPD, APHIS, USDA,

Room 1000, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782. Please state that your comments refer to Docket No. 88-014. Comments received may be inspected at the APHIS Public Reading Room, Room 1141, U.S. Department of Agriculture, 14th and Independence Avenue, SW., Washington, DC, 8:00 a.m. to 4:30 p.m., Monday through Friday, except holidays.

FOR FURTHER INFORMATION CONTACT: Dr. R.L. Crawford, Animal Care Staff, REAC, APHIS, USDA, Room 288, Federal Building, 8505 Belcrest Road, Hyattsville, MD 20782, (301) 436-7833.

SUPPLEMENTARY INFORMATION:

Background

In a document published in the Federal Register, on March 31, 1987 (52 FR 10298-10322), we proposed to revise the regulations contained in 9 CFR 2.1 through 2.130. These regulations pertain to licensing of dealers and exhibitors and registration of facilities and common carriers; recordkeeping for and identification of animals; holding periods and facilities; inspections; Institutional Animal Care and Use Committees; adequate veterinary care; and other areas relating to the humane care, handling, treatment, and transportation of animals. These changes have been proposed under the authority of the Animal Welfare Act (the Act), as amended (7 U.S.C. 2131, *et seq.*). They include some specific new requirements mandated by the 1985 amendments to the Act, contained in Pub. L. 99-198, "The Food Security Act of 1985," enacted December 23, 1985. The Act requires the Department to promulgate regulations and standards governing the humane handling, housing, care, treatment and transportation of certain animals by dealers, research facilities, exhibitors, carriers, and intermediate handlers. The standards and regulations must include minimum requirements with respect to handling, housing, feeding, sanitation, veterinary care, the use of pain relieving drugs, exercise for dogs, psychological well-being of nonhuman primates, recordkeeping, and other matters specified in section 13 of the Act, as amended (7 U.S.C. 2143).

We solicited comments concerning the proposal for a 60-day period ending June 1, 1987. The comment period was twice extended and ended on August 27, 1987. We did not consider comments and materials received after the closing date of August 27, 1987. We received a total of 7,857 comments addressing our proposal for Parts 1 and 2; 1,438 were