

Proposed Rules

Federal Register

Vol. 68, No. 70

Friday, April 11, 2003

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 2

[Docket No. 97-033-1]

Animal Welfare; Medical Records

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the Animal Welfare Act regulations to require that research facilities, dealers, and exhibitors maintain medical records as part of their program of adequate veterinary care. We believe research facilities, dealers, and exhibitors should maintain medical records as a means of communication concerning the care being provided to animals and to ensure that animals receive adequate veterinary care. In addition, these records would provide a basis for the Animal and Plant Health Inspection Service to better assess the veterinary care programs of research facilities, dealers, and exhibitors.

DATES: We will consider all comments that we receive on or before June 10, 2003.

ADDRESSES: You may submit comments by postal mail/commercial delivery or by e-mail. If you use postal mail/commercial delivery, please send four copies of your comment (an original and three copies) to: Docket No. 97-033-1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737-1238. Please state that your comment refers to Docket No. 97-033-1. If you use e-mail, address your comment to regulations@aphis.usda.gov. Your comment must be contained in the body of your message; do not send attached files. Please include your name and address in your message and "Docket No. 97-033-1" on the subject line.

You may read any comments that we receive on this docket in our reading

room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690-2817 before coming.

APHIS documents published in the **Federal Register**, and related information, including the names of organizations and individuals who have commented on APHIS dockets, are available on the Internet at <http://www.aphis.usda.gov/ppd/rad/webrepor.html>.

FOR FURTHER INFORMATION CONTACT: Dr. Jerry DePoyster, Senior Veterinary Medical Officer, Animal Care, APHIS, 4700 River Road Unit 84, Riverdale, MD 20737-1231; (301) 734-7586.

SUPPLEMENTARY INFORMATION:

Background

The Animal Welfare Act (the Act) (7 U.S.C. 2131 *et seq.*) authorizes the Secretary of Agriculture to promulgate standards and other requirements governing the humane handling, housing, care, treatment, and transportation of certain animals by dealers, research facilities, exhibitors, carriers, and intermediate handlers. The Secretary of Agriculture has delegated the responsibility of enforcing the Act to the Administrator of the Animal and Plant Health Inspection Service (APHIS). The regulations established under the Act are contained in title 9 of the Code of Federal Regulations (9 CFR), chapter I, subchapter A, parts 1, 2, and 3. Subparts C and D of 9 CFR part 2 (§§ 2.30 through 2.40, referred to below as the regulations) require, among other things, that each research facility, dealer, and exhibitor have an attending veterinarian and maintain a program of adequate veterinary care.

Currently, § 2.33(b), regarding research facilities, and § 2.40(b), regarding dealers and exhibitors, describe the elements that must be included in a program of adequate veterinary care. These elements include: (1) The availability of appropriate facilities, personnel, equipment, and services; (2) the use of appropriate methods to prevent, control, diagnose, and treat diseases and injuries and the availability of emergency, weekend, and holiday care; (3) daily observation of all

animals for health assessment; (4) guidance to principal investigators and other personnel involved in the care and use of animals regarding handling, immobilization, anesthesia, analgesia, tranquilization, and euthanasia; and (5) adequate pre- and post-procedural care according to current established veterinary medical and nursing procedures. Sections 2.33(b)(3) and 2.40(b)(3) further provide that a mechanism of direct and frequent communication is required so that timely and accurate information on problems of animal health, behavior, and well-being is conveyed to the attending veterinarian.

While maintenance of medical records is implied through our requirements for adequate veterinary care, the regulations do not specifically stipulate the maintenance of medical records as one of the elements in a program of adequate veterinary care. Medical records are an essential part of any program of adequate veterinary care. Adequate veterinary care can only be provided to animals if an accurate medical history is maintained on the animals to provide communication among all personnel involved in providing care. In addition, medical records provide a basis for APHIS inspectors to assess a veterinary care program and ensure that animals receive adequate veterinary care.

Therefore, we propose to add new §§ 2.33(b)(6) and 2.40(b)(6) to the regulations to include the maintenance of legible medical records as an additional element of the program of adequate veterinary care required by the regulations. To ensure that medical records include, at a minimum, information such as the vaccination history, surgical history, and any known drug sensitivities of the animals, we would specify that each medical record must include: (1) The identity of the animal (with the exception that routine husbandry, such as vaccinations, preventive medical procedures, or treatments, performed on all animals in a group (or herd) may be kept on a single record); (2) the date, description of the problem, pertinent history, observations, examination findings, test results, and plan for treatment and care with a tentative diagnosis and a prognosis, when appropriate; (3) the type and chronology of treatment procedures performed, the context of

the problem to which the treatment procedures pertain, and the identification of the medication used, the date given, dosage, route of administration, frequency, and duration of treatment; (4) the names of all vaccines administered and the dates of vaccination; and (5) the dates and results of all screening, routine, or other required or recommended tests.

Amending the regulations to specifically include requirements for maintaining medical records would necessitate changes to the provisions of the regulations regarding recordkeeping requirements for research facilities, dealers, and exhibitors. Section 2.35 pertains to the recordkeeping requirements for research facilities, and paragraph (f) of that section stipulates that records and reports must be maintained for at least 3 years. We would amend the recordkeeping requirements for research facilities in § 2.35(f) to require that medical records be kept for 1 year after the disposition of the animals and that one copy of those records be provided to subsequent owners of the animals or to any person to whom the animals are consigned. The retention period for all other records and reports would continue to be 3 years.

We would amend § 2.75, regarding recordkeeping by dealers and exhibitors, by adding a new paragraph (b)(4) requiring that one copy of the medical records be provided to subsequent owners of the animals or to any other person to whom the animals are consigned. Because § 2.80 currently contains a requirement that dealers and exhibitors, among others, retain records for 1 year after the disposition of the animals, we would not need to provide a specific retention period for medical records.

Executive Order 12866 and Regulatory Flexibility Act

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

This proposed rule would amend the Animal Welfare Act regulations to require that research facilities, dealers, and exhibitors maintain medical records as part of their program of adequate veterinary care. Currently, the maintenance of medical records is not specifically listed as one of the elements of a program of adequate veterinary care. However, we believe that requiring research facilities, dealers, and exhibitors to maintain medical records

would help ensure that animals receive adequate veterinary care. In addition, these records would provide a basis for APHIS to better assess the veterinary care programs of research facilities, dealers, and exhibitors.

In fiscal year 2000, there were 8,773 facilities of all sizes licensed or registered under the Act, including 4,612 dealers; 2,508 exhibitors; and 1,265 research facilities. Most research facilities are large relative to other regulated entities, and the average number of animals per research facility in fiscal year 2000 was 1,027.¹ This rule would affect those facilities that provide veterinary care.

In 1997, there were 10,045 U.S. farms in North American Industry Classification System (NAICS) category 11299 (All Other Animal Production, which includes dog and cat breeders/dealers), and the average annual sales per farm for that year was \$105,624, well below the U.S. Small Business Administration's (SBA) small entity threshold of \$750,000. In addition, in 1997, there were 4,607 U.S. firms in NAICS 541710 (Research and Development in the Physical, Engineering, and Life Sciences, which includes research facilities) that operated for the full year, and 99 percent of those firms had fewer than 500 employees, which is the SBA's small entity threshold for firms in NAICS 541710. In 1997, there were 498 firms in NAICS 711190 (Other Performing Arts Companies, which includes circus exhibitors) that operated for the full year, and 99 percent of those firms had less than \$5 million in sales that year, which is the SBA's small entity threshold for firms in NAICS 711190.

APHIS does not anticipate a great increase in burden to regulated entities. Almost all research facilities and more than 75 percent of other regulated facilities already comply with these proposed minimum standards for medical records. However, there may be a few entities that would need to improve the recordkeeping already in place, thus increasing their burden at least temporarily. We anticipate that the costs associated with any increase in burden would be minimal and would be limited primarily to the salary costs for the employee or employees responsible for assembling the documentation necessary to establish a medical record

that contains the information described in this proposed rule.

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

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

Executive Order 12988

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

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB). Please send written comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for APHIS, Washington, DC 20503. Please state that your comments refer to Docket No. 97-033-1. Please send a copy of your comments to: (1) Docket No. 97-033-1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737-1238, and (2) Clearance Officer, OCIO, USDA, room 404-W, 14th Street and Independence Avenue SW., Washington, DC 20250. A comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication of this proposed rule.

This proposed rule would amend the Animal Welfare Act regulations by requiring research facilities, dealers, and exhibitors to maintain medical records as part of their program of adequate veterinary care. We would require medical records to include: (1) The identity of the animal (with the exception that routine husbandry, such as vaccinations, preventive medical procedures, or treatments, performed on all animals in a group (or herd) may be

¹ See APHIS' Animal Welfare Enforcement Report for Fiscal Year 2000, available on the Internet at <http://www.aphis.usda.gov/ac/publications.html>. The average of 1,027 animals per research facility is based on 1,265 total facilities (1,231 active facilities and 34 inactive facilities).

kept on a single record); (2) the date, description of the problem, pertinent history, observations, examination findings, test results, and plan for treatment and care with a tentative diagnosis and a prognosis, when appropriate; (3) the type and chronology of treatment procedures performed, the context of the problem to which the treatment procedures pertain, and the identification of the medication used, the date given, dosage, route of administration, frequency, and duration of treatment; (4) the names of all vaccines administered and the dates of vaccination; and (5) the dates and results of all screening, routine, or other required or recommended tests.

In addition, we would amend the regulations regarding recordkeeping requirements for research facilities, dealers, and exhibitors. Specifically, we would amend the recordkeeping requirements for research facilities in § 2.35(f) to require that medical records be kept for 1 year after the disposition of the animals and that one copy of those records be provided to subsequent owners of the animals or to any person to whom the animals are consigned. We would amend § 2.75, regarding recordkeeping by dealers and exhibitors, by adding a new paragraph (b)(4) requiring that one copy of the medical records be provided to subsequent owners of the animals or to any other person to whom the animals are consigned.

We are soliciting comments from the public (as well as affected agencies) concerning our proposed information collection and recordkeeping requirements. These comments will help us:

(1) Evaluate whether the proposed information collection is necessary for the proper performance of our agency's functions, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the information collection on those who are to respond (such as through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology; e.g., permitting electronic submission of responses).

Estimate of burden: Public reporting burden for this collection of information is estimated to average 0.083 hours per response.

Respondents: Research facilities, dealers, and exhibitors.

Estimated annual number of respondents: 8,000.

Estimated annual number of responses per respondent: 691,975.

Estimated annual number of responses: 5,535,800.

Estimated total annual burden on respondents: 459,605 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

Copies of this information collection can be obtained from Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 734-7477.

Government Paperwork Elimination Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the Government Paperwork Elimination Act (GPEA), which requires Government agencies in general to provide the public the option of submitting information or transacting business electronically to the maximum extent possible. For information pertinent to GPEA compliance related to this proposed rule, please contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 734-7477.

List of Subjects in 9 CFR Part 2

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

Accordingly, we propose to amend 9 CFR part 2 as follows:

PART 2—REGULATIONS

1. The authority citation for part 2 would continue to read as follows:

Authority: 7 U.S.C. 2131–2159; 7 CFR 2.22, 2.80, and 371.7.

2. In § 2.33, paragraph (b) would be amended as follows:

a. In paragraph (b)(4), by removing the word “and” immediately after the semicolon.

b. In paragraph (b)(5), by removing the period and adding the word “; and” in its place.

c. By adding new paragraph (b)(6) to read as set forth below.

§ 2.33 Attending veterinarian and adequate veterinary care.

* * * * *

(b) * * *

(6) The maintenance of medical records is a required component of adequate veterinary care. They serve as a basis for reviewing the medical history and planning veterinary care and provide a mechanism of communication

for matters of animal health, behavior, and well-being. Medical records document the animal's illness, veterinary care, and treatment and serve as a basis for review, study, and evaluation of veterinary care rendered by the facility. Medical records must be legible and include at least the following information:

(i) The identity of the individual animal; *Provided, however,* That routine husbandry, such as vaccinations, preventive medical procedures, or treatments, performed on all animals in a group (or herd) may be kept on a single record;

(ii) The date, description of the problem, pertinent history, observations, examination findings, test results, and plan for treatment and care with a tentative diagnosis and a prognosis, when appropriate;

(iii) The type and chronology of treatment procedures performed, the context of the problem to which the treatment procedures pertain, and the identification of the medication used, the date given, dosage, route of administration, frequency, and duration of treatment;

(iv) The names of all vaccines administered and the dates of vaccination; and

(v) The dates and results of all screening, routine, or other required or recommended tests.

3. In § 2.35, paragraph (f), the first sentence would be removed and two new sentences would be added in its place to read as follows:

§ 2.35 Recordkeeping requirements.

* * * * *

(f) The medical records required under § 2.33(b)(6) shall be kept for at least 1 year after the disposition of the animal, and a copy shall be given to the subsequent owner of the animal or to any person to whom the animal is consigned. All other records and reports shall be maintained for at least 3 years.

* * *

4. In § 2.40, paragraph (b) would be amended as follows:

a. In paragraph (b)(4), by removing the word “and” immediately after the semicolon.

b. In paragraph (b)(5), by removing the period and adding the word “; and” in its place.

c. By adding new paragraph (b)(6) to read as set forth below.

§ 2.40 Attending veterinarian and adequate veterinary care (dealers and exhibitors).

* * * * *

(b) * * *

(6) The maintenance of medical records is a required component of

adequate veterinary care. They serve as a basis for reviewing the medical history and planning veterinary care and provide a mechanism of communication for matters of animal health, behavior, and well-being. Medical records document the animal's illness, veterinary care, and treatment and serve as a basis for review, study, and evaluation of veterinary care rendered by the facility. Medical records must be legible and include at least the following information:

(i) The identity of the individual animal; *Provided, however*, That routine husbandry, such as vaccinations, preventive medical procedures, or treatments, performed on all animals in a group (or herd), may be kept on a single record;

(ii) The date, description of the problem, pertinent history, observations, examination findings, test results, and plan for treatment and care with a tentative diagnosis and a prognosis, when appropriate;

(iii) The type and chronology of treatment procedures performed, the context of the problem to which the treatment procedures pertain, and the identification of the medication used, the date given, dosage, route of administration, frequency, and duration of treatment;

(iv) The names of all vaccines administered and the dates of vaccination; and

(v) The dates and results of all screening, routine, or other required or recommended tests.

5. In § 2.75, a new paragraph (b)(4) would be added to read as follows:

§ 2.75 Records: Dealers and exhibitors.

* * * * *

(b) * * *

(4) One copy of the medical records containing the information required by § 2.40(b)(6) shall be provided to the subsequent owner of the animal or to any person to whom the animal is consigned.

Done in Washington, DC, this 7th day of April 2003.

Peter Fernandez,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 03-8928 Filed 4-10-03; 8:45 am]

BILLING CODE 3410-34-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2001-NM-401-AD]

RIN 2120-AA64

Airworthiness Directives; Aerospatiale Model ATR72 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to certain Aerospatiale Model ATR72 series airplanes. This proposal would require installing brackets and ramps under floor panels between frames 23C and 23D, and installing wire bundles on the ramps. This action is necessary to prevent chafing damage to the electrical wire cables, which could lead to an electrical short circuit and potential for a fire under the floor panels. This action is intended to address the identified unsafe condition.

DATES: Comments must be received by May 12, 2003.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM-114, Attention: Rules Docket No. 2001-NM-401-AD, 1601 Lind Avenue, SW., Renton, Washington 98055-4056. Comments may be inspected at this location between 9 a.m. and 3 p.m., Monday through Friday, except Federal holidays. Comments may be submitted via fax to (425) 227-1232. Comments may also be sent via the Internet using the following address: 9-anm-nprmcomment@faa.gov. Comments sent via fax or the Internet must contain "Docket No. 2001-NM-401-AD" in the subject line and need not be submitted in triplicate. Comments sent via the Internet as attached electronic files must be formatted in Microsoft Word 97 for Windows or ASCII text.

The service information referenced in the proposed rule may be obtained from Aerospatiale, 316 Route de Bayonne, 31060 Toulouse, Cedex 03, France. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Dan Rodina, Aerospace Engineer, International Branch, ANM-116, FAA, Transport Airplane Directorate, 1601

Lind Avenue, SW., Renton, Washington 98055-4056; telephone (425) 227-2125; fax (425) 227-1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this action may be changed in light of the comments received.

Submit comments using the following format:

- Organize comments issue-by-issue. For example, discuss a request to change the compliance time and a request to change the service bulletin reference as two separate issues.
- For each issue, state what specific change to the proposed AD is being requested.
- Include justification (e.g., reasons or data) for each request.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this action must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 2001-NM-401-AD." The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM-114, Attention: Rules Docket No. 2001-NM-401-AD, 1601 Lind Avenue, SW., Renton, Washington 98055-4056.

Discussion

The Direction Générale de l'Aviation Civile (DGAC), which is the airworthiness authority for France, notified the FAA that an unsafe condition may exist on certain Aerospatiale Model ATR72 series