

1993, and published in the Federal Register on January 28, 1993 (58 FR 6343-6346, Docket No. 91-155-4), we amended the regulations by expanding the previously quarantined area in Los Angeles County, and including a portion of Orange County, and by adding a portion of San Diego County, CA, to the list of quarantined areas.

Based on trapping surveys by inspectors of California State and county agencies and by inspectors of the Animal and Plant Health Inspection Service we have determined that the Medfly has been eradicated from the quarantined area in San Diego County, CA. The last finding of the Medfly thought to be associated with the infestation in this area was made on November 11, 1992. Since then, no evidence of infestation has been found in this area. We have determined that the Medfly no longer exists in this area, and we are therefore removing it from the list of areas in § 301.78-3(c) quarantined because of the Mediterranean fruit fly. As a result of this action there are no longer any quarantined areas in San Diego County. Portions of Los Angeles, Orange and Santa Clara Counties remain quarantined.

Immediate Action

The Administrator of the Animal and Plant Health Inspection Service has determined that there is good cause for publishing this interim rule without prior opportunity for public comment. The area in California affected by this document was quarantined due to the possibility that the Mediterranean fruit fly could spread to noninfested areas of the United States. Since this situation no longer exists, and the continued quarantined status of this area would impose unnecessary regulatory restrictions on the public, immediate action is warranted to remove restrictions from the noninfested areas.

Because prior notice and other public procedures with respect to this action are impracticable and contrary to the public interest under these conditions, we find good cause under 5 U.S.C. 553 to make it effective upon signature. We will consider comments that are received within 60 days of publication of this rule in the Federal Register. After the comment period closes, we will publish another document in the Federal Register. It will include a discussion of any comments we receive and any amendments we are making to the rule as a result of the comments.

Executive Order 12291 and Regulatory Flexibility Act

We are issuing this rule in conformance with Executive Order 12291, and we have determined that it is not a "major rule." Based on information compiled by the Department, we have determined that this rule will have an effect on the economy of less than \$100 million; will not cause a major increase in costs or prices for consumers, individual industries, Federal, State or local government agencies, or geographic regions; and will not cause a significant adverse effect on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

For this action, the Office of Management and Budget has waived the review process required by Executive Order 12291.

This rule affects the interstate movement of regulated articles from the Oceanside area of San Diego County in California. There are approximately 132 small entities that could be affected, including 40 retail/wholesale fruit stands, 59 nurseries, 3 packers, 2 farmers' markets, and 25 fruit vendors. There are also 3 farms totalling 2.7 acres.

The effect of this rule on these entities should be insignificant since most of these small entities handle regulated articles primarily for local intrastate movement, not interstate movement, and the distribution of these articles was not affected by the regulatory provisions we are removing.

Many of these entities also handle other items in addition to the regulated articles so that the effect, if any, of this regulation on these entities should be minimal. Further, the conditions in the Mediterranean fruit fly regulations and treatments in the Plant Protection and Quarantine Treatment Manual, incorporated by reference in the regulations, allow the interstate movement of most articles without significant added costs. These small entities comprise less than 1 percent of the total number of similar entities operating in the State of California.

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

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance

under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

Executive Order 12778

This rule has been reviewed under Executive Order 12778, Civil Justice Reform. This rule:

- (1) Preempts all State and local laws and regulations that are inconsistent with this rule;
- (2) Has no retroactive effect; and
- (3) Does not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

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

List of Subjects in 7 CFR Part 301

Agricultural commodities, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Transportation.

Accordingly, 7 CFR part 301 is amended to read as follows:

PART 301—DOMESTIC QUARANTINE NOTICES

1. The authority citation for 7 CFR part 301 continues to read as follows:

Authority: 7 U.S.C. 150bb, 150dd, 150ee, 150ff; 161, 162, and 164-167; 7 CFR 2.17, 2.51, and 371.2(c).

§ 301.78-3 [Amended]

2. In § 301.78-3, paragraph (c) is amended by removing the entry for San Diego County.

Done in Washington, DC, this 16th day of July 1993.

Eugene Bransteol,

Assistant Secretary, Marketing and Inspection Services.

[FR Doc. 93-17438 Filed 7-21-93; 8:45 am]

BILLING CODE 3410-34-P

9 CFR Parts 1 and 2

[Docket No. 91-035-3]

RIN 0579-AA42

Random Source Dogs and Cats

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the regulations under the Animal Welfare Act (Act) to require that dogs and cats acquired by pounds and shelters owned

and operated by States, counties, and cities, private entities established for the purpose of caring for animals, such as humane societies or contract pounds or shelters, and research facilities licensed as dealers by the United States Department of Agriculture, be held and cared for at those establishments for at least 5 days before being provided to a dealer. We are also amending the regulations to require that dealers provide a valid certification to anyone acquiring random source dogs and cats from them. These amendments are being made pursuant to the most recent amendment of the Act. The amendment to the Act was enacted to prevent the use of stolen pets in research and to provide owners the opportunity to locate their animals.

EFFECTIVE DATE: August 23, 1993.

FOR FURTHER INFORMATION CONTACT: Dr. R.L. Crawford, Acting Assistant Deputy Administrator, Animal Care, Regulatory Enforcement and Animal Care, APHIS, USDA, room 554, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, (301) 436-4981.

SUPPLEMENTARY INFORMATION:

Background

The Animal Welfare Regulations (the regulations) are contained in title 9 of the Code of Federal Regulations, chapter 1, subchapter A, parts 1, 2, and 3. Part 1 provides definitions of the terms used in parts 2 and 3. Part 2 sets forth the administrative and institutional responsibilities of regulated persons under the Animal Welfare Act (7 U.S.C. 2131, *et seq.*) (the Act). Part 3 provides specifications for the humane handling, care, treatment, and transportation, by regulated persons, of animals covered under the Act.

On November 15, 1992, we published in the Federal Register (56 FR 57991-57994, Docket No. 91-035) a document proposing to add new provisions to 9 CFR part 2, subpart I, regarding the length of time certain pounds, shelters, and research facilities must hold dogs and cats, in accordance with the Act. We also proposed to add to 9 CFR part 2, subpart I, provisions requiring certification to accompany random source dogs and cats sold, provided, or made available by dealers to any individual or entity.

We invited comments on our proposed rule, requiring that they be received on or before December 16, 1991. We received 49 comments by that date. The commenters included members of the academic and research communities, biological supply companies, municipal animal holding facilities, humane organizations, and

other members of the general public. A number of the commenters requested that the comment period be extended. We made no changes to the comment period based on these requests. We consider the 30-day comment period provided to have been sufficient time for the public to have reviewed and responded to the proposed rule.

Of the commenters that addressed the proposed rule, one opposed it in general. The remainder of the commenters recommended specific changes to the proposed provisions. We carefully considered all comments, and discuss the commenters' recommendations below. Based on the reasons set forth in the proposal and in this document, we are adopting the provisions of the proposed rule, with the changes discussed in this document.

Holding Period

In proposed § 2.133 (a)(1) through (a)(3), we proposed that any dog or cat acquired by (1) a State, county, or city owned and operated pound or shelter, (2) a private entity established for the purpose of caring for animals, such as a humane society, or other organization that is under contract with a State, county, or city, that operates as a pound or shelter, and that releases animals on a voluntary basis, or (3) a research facility which is licensed by the United States Department of Agriculture (USDA) as a dealer, must be held and provided care for at least 5 full days before being sold to a dealer. We proposed further that this 5-day period would not include the day of acquisition or time in transit. (Additionally, the day of disposition is also excluded from the holding period because it is not a full day.) We proposed that this holding period would include a Saturday, in order to provide owners and other individuals the opportunity to recover or adopt such animals on a weekend.

A number of commenters expressed concern that the 5-day holding period would significantly raise the operating costs of shelters that are not currently holding animals for that length of time, and that these costs would have to be passed along in the form of increased taxes or higher prices to dealers. In the latter case, said the commenters, the costs would then be passed along to colleges and universities that use the animals for research. One commenter recommended that a holding period of 10 days be required.

We are making no changes based on these comments. While we recognize that the rule may increase costs in some cases, the statute requires the establishment of at least a 5-day holding

period. The intent of the holding period is to provide a reasonable period of time for a dog or cat to be either recovered by its original owner or adopted by other individuals before the dog or cat is provided to a dealer. We continue to consider the holding period required by this rule to be consistent with that intent.

Several commenters specifically supported the provision that the holding period include a Saturday. One commenter opposed that provision, stating that Congress withdrew that requirement in conference before amending the Act. We are making no changes based on this comment. Although a Saturday holding requirement does not appear in the Act, the legislative history regarding the amendment to the Act clearly shows that Congress supported the concept of holding dogs and cats over a Saturday. We are confident that such a requirement will be, in many cases, a significant aid to owners attempting to recover lost pets.

A number of commenters stated that if the intent of the proposal was to give owners the opportunity to recover pets, then the 5-day holding period should be extended to all dogs and cats at pounds and shelters, not just to those sold to dealers. Some of these commenters stated that the number of dogs and cats sold to dealers is a small percentage of the total number of dogs and cats at pounds and shelters. We are making no changes based on these comments. The statute does not authorize imposition of such requirements.

A number of commenters recommended that the holding period be waived in cases where the owner of the dog or cat indicates that he or she allows the dog or cat to be used in research. Several commenters specifically opposed such a change to the proposal. One of these commenters expressed concern that such a provision would result in dogs and cats being fraudulently identified, unless the individual releasing the dog or cat were to show verifiable proof of ownership. We are making no changes to the regulations based on these comments. The intent of the 5-day holding period, as set forth in the Act, is both to enable dogs and cats to be recovered by their owners and to allow dogs and cats to be adopted by other individuals. Establishing an owner-option waiver would not further the goal of allowing additional time for adoption of dogs and cats.

A number of commenters recommended that the proposed holding period be applied only to live dogs and cats. Many of these

commenters stated that dogs and cats euthanized without being held for 5 days would likely be disposed of through other means, such as disposal at landfills or incinerators. The commenters expressed concern that this would reduce the supply and raise the cost of dead dogs and cats used for educational purposes. Upon consideration of these comments and of the amendment's provisions, we agree with the commenters. The purpose of the amendment is to provide pet owners a greater opportunity to recover any lost or stolen dogs and cats, and to allow others to adopt stray dogs and cats. The amendment does not require pounds and shelters to hold dogs and cats before euthanizing them. No purpose would be served by precluding pounds and shelters from selling or otherwise disposing of euthanized dogs and cats to dealers. Accordingly, the proposed regulations are modified in this final rule to make it clear that they apply only to live dogs and cats.

Several commenters requested that language be added to the proposed provisions to make clear that the holding period would apply only to dogs and cats acquired by dealers, and not to those made available by pounds and shelters directly to research facilities. Another commenter recommended that the holding period be extended to include any dog or cat released from a pound or shelter, regardless of whether it is sold directly to a research facility. We are making no changes based on these comments. The statute clearly states that the holding period applies only to dogs and cats provided to dealers. It should be noted, however, that research facilities that sell animals (other than those that are government-operated) must be licensed as "dealers," and therefore the holding period would apply in such cases.

One commenter objected to the provision that the holding period would exclude the time a dog or cat spends in transit, stating that this provision would be difficult to enforce. We do not agree. We are already enforcing regulations in 9 CFR part 2 that require dealers and exhibitors to meet certain holding periods, and these holding periods are exclusive of time dogs and cats are in transit. We have not found it difficult to enforce these regulations.

One commenter stated that, because of their functional differences, it is misleading to include pounds and shelters in the same definition. The commenter recommended that separate definitions be developed for each type of facility. We are making no changes based on this comment. Although there may be differences between pounds and

shelters in other contexts, when they engage in activities subject to the regulations there are no legally significant differences.

One commenter recommended that language be inserted into the proposed regulations to clarify that State laws prohibiting the release of pound and shelter dogs and cats would not be superseded. We are making no changes based on this comment. It is nowhere implied in the proposed regulations that pounds and shelters would be required to release dogs and cats to dealers.

Clarification

We are also making a change to the regulations as proposed to clarify which dogs and cats are subject to the holding period. In accordance with the statutory requirements, the certification requirements in proposed § 2.133(b) apply to random source dogs and cats acquired by a dealer from any person, pound, or shelter. However, proposed § 2.133(a) refers only to entities "selling" dogs or cats. Therefore, to eliminate any possible confusion, proposed § 2.133(a) is modified in this final rule to provide that the holding period will apply to dogs and cats that are sold or in any way "provided" to dealers by the entities described in § 2.133(a).

Certification

In our proposed rule, we also proposed to establish requirements for certification to accompany random source dogs and cats that are sold, provided, or otherwise made available by dealers to any individual or entity. A number of commenters recommended that the requirement that the dealer certify that the person, pound, or shelter releasing the dog or cat was informed that it might be used in research or education be changed to require that the notice be in writing. We are making no changes based on this comment. We consider the written certification adequate to facilitate our enforcement of the proposed provisions.

The certification as proposed would also have to include a description of the dog or cat, which would include the following: (1) The species, breed, or type; (2) the sex; (3) the date of birth or, if unknown, the approximate age; (4) the color and any distinctive markings; and (5) the official USDA-approved identification number of the dog or cat. Several commenters recommended that the description be required to include additional information, including length, height, and weight, and, for mixed breeds, an estimate of the dominant breeds. One commenter recommended that the regulations

require each dog or cat to be photographed.

We agree that mixed breeds could be better identified if an estimate were made of the dominant breeds or types. Therefore, § 2.133(b)(3)(i) as proposed is modified in this final rule to provide that, for mixed breeds, the certification must indicate an estimate of the two dominant breeds or types. We do not agree that adding length, height, and weight would aid significantly in identification. Except in infrequent situations, a dog or cat identified by its breed or mix will fall into an identifiable size range, and the specificity gained by actually measuring them would not justify the added burden involved. Weight would not necessarily be a good method of identification, because, in many cases, strays suffer significantly weight loss. We also do not agree that requiring that each dog or cat be photographed would be justifiable or necessary. We consider the information required by this final rule to be adequate for identification. The significant additional cost of photographing each dog or cat would not be justified by any additional specificity the photograph might provide.

Several commenters requested clarification of whether the certification requirements would apply to dogs and cats that have been euthanized, and objected to such an application. One commenter recommended that, if the regulations were to apply to dead animals, it be provided that the certification requirements cease with the first recipient of the animals. The commenters expressed concern that applying the certification requirements to dead animals would create unwieldy recordkeeping requirements for catalog supply houses, which, the commenters stated, would have to maintain certification records on specific animals through the processing cycle, send the specified certification records to the end use (schools), and require return of verification of receipt of such certification. We agree with these comments and, as stated above, the regulations as proposed are modified in this final rule to make it clear that they apply only to live dogs and cats.

Section 2.133(b)(4) as proposed provides that the certification that would have to accompany the dog or cat must contain the name and address of the person, pound, or shelter from which the dog or cat was acquired by the dealer. Proposed § 2.133(b)(5) provides, additionally, that the certification must include the date the dealer acquired the dog or cat. One commenter stated that these proposed

provisions are in conflict with current § 2.75(a)(4), which provides that the source and date of acquisition of a dog or cat need not appear on the copy of the record that must accompany the shipment under the current regulations. The commenter stated that the proposed regulations create a similar discrepancy under current § 2.35(e) with regard to registered research facilities that dispose of dogs and cats acquired from dealers to any other facility.

We agree that this apparent discrepancy could be confusing. The proposed regulations are intended to supplement the recordkeeping requirements in the current regulations in situations where random source dogs and cats are involved. In such cases, the proposed regulations would supersede the "freedom from disclosure" provisions in current §§ 2.75 and 2.35. Therefore, we are amending current §§ 2.75(a)(4) and 2.35(e) to clarify that the provisions in those sections that state that the date and source of acquisition of dogs and cats need not appear on records accompanying shipments of dogs and cats are applicable except as provided in § 2.133.

Section 2.133(b)(1) as proposed provides that the certification to accompany the dog or cat must include the name, address, USDA license number, and signature of any dealer providing a dog or cat covered by the proposed provisions to another party. One commenter recommended that this identification requirement be expanded to include the vehicle license number and State of the individual delivering the dog or cat, that individual's driver's license and State, and the State of the individual. The commenter stated that, because some dealers employ many employees and subcontractors, this additional identification would be necessary to resolve any theft problems. We are making no changes based on this comment. We consider the information available to us under § 2.75 of the current regulations ("Records: Dealers and exhibitors"), and in the regulations as proposed, to be sufficient to trace the address and location of any dealer supplying dogs or cats.

Section 2.133(g) as proposed requires that, in instances where a research facility transfers a random source dog or cat acquired from a dealer to another research facility, a copy of the required certification must accompany the dog or cat transferred. Several commenters requested clarification of whether the word "transfers" refers to an actual change of ownership, or simply to a physical transfer of the dog or cat for the purpose of maintaining it in a different

facility for part of a study. Another commenter recommended that the regulations specify that, in the case of two or more research institutions transferring dogs or cats among themselves, each facility must maintain copies of the certification. The word "transfers" as we used it in the proposal was intended to refer to change of ownership. If no change of ownership occurs, the records maintained by the first facility will be sufficient for identification and tracing of the animal. We are therefore amending § 2.133(g), as proposed, to read: "In instances where a research facility transfers ownership of a live random source dog or cat acquired from a dealer to another research facility, a copy of the certification required by paragraph (b) of this section must accompany the dog or cat transferred * * *."

Sections 2.133 (f) and (g) as proposed provide that research facilities must keep copies of the required certification for at least 1 year following disposition of the animal. One commenter stated that this period is not consistent with § 2.35(f) of the current regulations, which requires all registered research facilities to maintain acquisition and disposition records for dogs and cats for a minimum of 3 years. We agree that the record retention requirement should be consistent and should be 3 years. Accordingly, § 2.133(f) as proposed is modified in this final rule to provide that a research facility that acquires any random source dog or cat from a dealer shall keep, maintain, and make available for APHIS inspection a copy of the required certification for at least 3 years following disposition of the dog or cat. Also, § 2.133(g) as proposed is modified in this final rule to require that research facilities that obtain ownership from another research facility of a random source dog or cat acquired from a dealer shall keep, maintain, and make available for APHIS inspection a copy of the required certification for at least 3 years following disposition of the dog or cat.

Nonsubstantive Changes

We are changing the references to "the Department" in the rule to read "USDA." This change will make the terminology in the rule consistent with the terminology in the remainder of 9 CFR part 2. We are also updating the authority citation for this rule to reflect the most recent amendments to the act. Additionally, we are making nonsubstantive changes for purposes of clarity.

Public Comments on the Initial Regulatory Flexibility Analysis

As required by the Regulatory Flexibility Act (Pub. L. 96-354), we conducted an initial regulatory flexibility analysis regarding the proposed rule, and we encouraged comments on the analysis. We received a small number of comments regarding the analysis.

In our initial regulatory flexibility analysis, we assumed an average holding period of 3 days for dogs and cats at pounds and shelters. Several commenters suggested that we should have assumed a longer average holding period. These commenters stated that many shelters already hold dogs and cats for 5 or more days. While we agree that many shelters may hold dogs and cats for periods in excess of 3 days, we nonetheless believe that a 3-day average is a reasonable average upon which to base our analysis.

One commenter stated that our estimate that 2,200 to 3,800 pounds and shelters in the United States sell dogs and cats to dealers was too high, because many county and local laws prohibit the sale or release of dogs and cats to dealers. We agree that, in many cases, whether dogs and cats may be released to dealers is determined by the laws and ordinances of local jurisdictions. Because of this, it is impossible, without conducting a costly and comprehensive survey, to determine precisely how many facilities do release dogs and cats to dealers. That is why we provided such a wide range in our estimate, which we continue to consider a reasonable one based on the information available to us.

One commenter stated that our estimated numbers of dogs and cats sold or otherwise provided by pounds or shelters to dealers (80,000 for dogs and 50,000 for cats) were too high. The estimates we provided in our proposal were based on data from 1985-1990. Trends in the use of dogs and cats in research have been changing, and we agree with the commenter that the most recent figures available show a decline from previous years. Therefore, we have revised our estimates of the number of dogs and cats sold or provided annually from pounds and shelters to 67,000 dogs and 31,000 cats.

One commenter felt that the \$7 figure we used as the cost per day to care for each dog or cat was too high. We based this figure on 30 minutes of labor and \$1-\$3 worth of food, cleaning materials, and water. We consider it to be a reasonable cost figure.

Several commenters suggested that shelters are generally full, and that, in

order to hold dogs and cats for 5 days, additional space and cages would be necessary at these facilities. Although we agree that some pounds and shelters may often be used to capacity, it would be extremely costly and difficult to determine how much pound or shelter capacity is utilized on a daily or weekly basis across the United States. The regulations in this rule, however, do not apply to all dogs and cats held at pounds or shelters, but only to those provided to dealers. Therefore, pounds and shelters that generally operate at capacity would have to add space only if they wanted to sell dogs and cats to dealers. At this time, we have no way of determining how many dogs and cats will be provided to dealers once the provisions in this rule are implemented.

Several commenters questioned the statement in the initial regulatory flexibility analysis that the increased costs arising from the proposed regulation would be borne by taxpayers. We agree that this statement may be an oversimplification. Increased costs faced by pounds and shelters as a result of this rule will need to be absorbed by the pound or shelter either through: (1) increased funding from either private donations, or State, county, or city funds, or (2) increased income from the sale of each dog or cat. This statement is included in the regulatory flexibility analysis discussed below.

In our initial regulatory flexibility analysis, we stated that the sales of dogs and cats from pounds and shelters are currently prohibited in 12 states. One commenter correctly stated that a thirteenth state, West Virginia, also prohibits such sales, and we have amended our analysis accordingly.

Miscellaneous

A number of commenters addressed issues outside the scope of the proposal. One commenter recommended that it be required that owners who voluntarily deliver a dog or cat to a pound or shelter be informed in writing if that facility might transfer the animal to a dealer or research facility. One commenter requested that the definition of dealer in 9 CFR part 1 be amended to exclude "a pound/shelter municipally owned and operated or a pound or shelter operated under contract with a State, county, city, or other jurisdiction." One commenter expressed the opinion that it is essential that the pet-owning public have free access to animals at a pound or shelter during regular business hours and a Saturday. One commenter recommended that we consider a more permanent form of identification for dogs and cats than that required by the current regulations. The same

commenter requested that we license pounds and shelters that sell animals for research or education purposes as "Class B dealers." (We are already following such a practice, except with regard to municipal pounds and shelters.) One commenter recommended that dealers that also operate pounds or shelters be liable for proper care of the animals present. (Standards for such care already exist in 9 CFR part 3, subpart A.) One commenter requested that AHIS investigate means by which the perception that pets are widely used in research could be corrected, and also that APHIS conduct a study of the effectiveness and impact of the proposed rule, once implemented, and present it to Congress. Although we are making no changes based on these comments, we have reviewed them carefully, and, if necessary, will take whatever action is appropriate.

Executive Order 12291 and Regulatory Flexibility Act

We are issuing this rule in conformance with Executive Order 12291, and we have determined that it is not a "major rule." Based on information compiled by the Department, we have determined that this rule will have an effect on the economy of less than \$100 million; will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and will not cause a significant adverse effect on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

Regulatory Flexibility Analysis

In accordance with 5 U.S.C. 603, we have performed a regulatory flexibility analysis regarding the potential impact of this rule on small entities. This analysis is set forth below.

Under this rule, municipally owned and operated pounds and shelters, humane societies and contract pounds or shelters, and licensed research facilities that provide random source dogs and cats to dealers must comply with the holding period. Sales of dogs and cats for research from pounds and shelters are currently prohibited in the following 13 States: Connecticut, Delaware, Hawaii, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, and Vermont, and West Virginia. Pounds and shelters in these 13 States would, therefore, be unaffected by the proposed regulations. Individual

shelters in the remaining 37 States and the District of Columbia that choose not to make such sales would also be unaffected. Under part 2, subpart C, § 2.38(j) of the Animal Welfare regulations, research facilities are already required to hold for 5 full days dogs or cats that they acquire from sources other than dealers, exhibitors and exempt persons. The only change from the current regulations in this regard would be the addition of the requirement that the dogs and cats at licensed research facilities be held over at least one Saturday.

The total number of pounds and shelters in the United States is estimated by the Humane Society of the United States to be between 3,000, 5,000. For purpose of the Regulatory Flexibility Act, all of these pounds and shelters would be considered small. For this analysis, it was assumed that approximately 2,200 to 3,800 pounds and shelters in the United States may sell dogs and cats to dealers. It is estimated that as many as 67,000 dogs and 31,000 cats may be sold or provided to dealers from these pounds and shelters each year. These 2,200 to 3,800 pounds and shelters will be affected by the regulations. The extent of the impact of the regulation on these pounds and shelters will depend on whether the pound or shelter currently holds dogs and cats at least 5 days, including a Saturday, before selling them to a dealer.

Holding periods for pounds and shelters are currently prescribed by State or local governments and by shelter operators. While it was known that at least one State, Minnesota, requires dogs and cats to be held for 5 days before they can be sold, specific information for other State and local governments was not available. A 3-day average holding period was assumed for this analysis. Therefore, this regulation will require pounds and shelters to hold and care for each dog or cat, on average, for an additional 2 to 4 days, in order to hold each dog and cat for 5 days including a Saturday. The daily cost for labor and materials to feed, water, and clean up after each dog or cat was estimated at \$7. The increased cost to each affected pound or shelter for each dog or cat is, therefore, estimated at approximately \$14 to \$28. The increased annual cost for each affected shelter is estimated at approximately \$370 to \$1,250.

Some of the pounds or shelters that sell, provide, or make available dogs or cats to dealers may currently be operating at capacity. The holding requirements set forth in this rule may result in these pounds and shelters

adding space and/or cages. It was not possible to determine how many pounds or shelters might be affected in this manner or to estimate the cost of this impact.

To absorb the increased costs resulting from this rule, pounds and shelters must either increase their funding and/or increase their income from the sale of each dog or cat. Increased funding could come from increased private donations or increased monies from State, county, or city finances. Taxpayers and purchasers of these dogs and cats could be affected.

Under this rule, any dealer selling, providing, or making available to any person a random source dog or cat will be required to provide the recipient of the dog or cat with certain certification, as discussed in the supplementary information of this document under the heading "Certification." These proposed requirements overlap the current provisions of part 2 of the Animal Welfare regulations. Under the regulations prior to the effective date of this rule, dealers are already required to enclose a record with each shipment of any dog or cat. This record must contain the following:

1. The name and address of the person to whom a dog or cat was sold or given and that person's license or registration number if he or she is licensed or registered under the Act;
2. The official USDA tag number or tattoo assigned to a dog or cat; and
3. A description of the dog or cat.

Dealers are also currently required to maintain records of the following information for each dog or cat:

1. The name and address of the person from whom a dog or cat was purchased or otherwise acquired, whether or not the person is required to be licensed or registered under the Act;
2. The USDA license or registration number of the person if he or she is licensed or registered under the Act;
3. The vehicle license number and state, and the driver's license number and State, and State of the person, if he or she is not licensed or registered under the Act;

4. The date a dog or cat was acquired or disposed of, including by euthanasia;
5. The method of transportation, including the name of the initial carrier or intermediate handler or, if a privately owned vehicle is used to transport a dog or cat, the name of the owner of the privately owned vehicle; and
6. The date and method of disposition of a dog or cat—e.g., sale, death, euthanasia, or donation.

Because, as noted above, the certification requirements contained in this rule are comprised in large measure

of information already required, the reporting requirements of this regulation are not expected to increase dealers' cost.

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 12778

This final rule has been reviewed under Executive Order 12778, 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 of the Paperwork Reduction Act of 1980 (44 U.S.C. chapter 35), the information collection provisions that are included in this rule have been approved by the Office of Management and Budget (OMB) and have been given OMB control number 0579-0036.

List of Subjects

9 CFR Part 1

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

9 CFR Part 2

Adequate veterinary care, Identification of animals, Institutional animal care and use committees, Licensing, Miscellaneous, Records, Registration.

Accordingly, 9 CFR parts 1 and 2 are amended as follows:

PART 1—DEFINITION OF TERMS

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

Authority: 7 U.S.C. 2131-2159; 7 CFR 2.17, 2.51, and 371.2(g).

2. Section 1.1 is amended by adding, in alphabetical order, a definition of "Pound or shelter" to read as follows:

§1.1 Definitions.

Pound or shelter means a facility that accepts and/or seizes animals for the purpose of caring for them, placing them through adoption, or carrying out

law enforcement, whether or not the facility is operated for profit.

PART 2—REGULATIONS

3. The authority citation for part 2 is revised to read as follows:

Authority: 7 U.S.C. 2131-2159; 7 CFR 2.17, 2.51, and 371.2(g).

4. In subpart C, § 2.35(e) is amended by revising the first sentence to read as follows:

§ 2.35 Recordkeeping requirements.

(e) One copy of the record containing the information required by paragraphs (b) and (c) of this section shall accompany each shipment of any live dog or cat sold or otherwise disposed of by a research facility; *Provided, however, That, except as provided in § 2.133 of this part, information that indicates the source and date of acquisition of any dog or cat need not appear on the copy of the record accompanying the shipment.*

5. In subpart C, § 2.38, a new paragraph (k)(4) is added to read as follows:

§ 2.38 Miscellaneous.

(k) * * *

- (4) Each research facility shall comply with the regulations set forth in § 2.133 of subpart I of this part.

6. In subpart C, § 2.75(a)(4) is amended by revising the second sentence to read as follows:

§ 2.75 Records: Dealers and exhibitors.

(a) * * *

- (4) * * * One copy of the record containing the information required by paragraph (a)(1) of this section shall accompany each shipment of any dog or *however, that, except as provided in § 2.133(b) of this part for dealers, information that indicates the source and date of acquisition of a dog or cat need not appear on the copy of the record accompanying the shipment.*

7. Part 2, subpart I, is amended by adding a new § 2.133 to read as follows:

§ 2.133 Certification for random source dogs and cats.

(a) Each of the entities listed in paragraphs (a)(1) through (a)(3) of this section that acquire any live dog or cat shall, before selling or providing the live dog or cat to a dealer, hold and care for the dog or cat for a period of not less

than 5 full days after acquiring the animal, not including the date of acquisition and excluding time in transit. This holding period shall include at least one Saturday. The provisions of this paragraph apply to:

(1) Each pound or shelter owned and operated by a State, county, or city;

(2) Each private pound or shelter established for the purpose of caring for animals, such as a humane society, or other organization that is under contract with a State, county, or city, that operates as a pound or shelter, and that releases animals on a voluntary basis; and

(3) Each research facility licensed by USDA as a dealer.

(b) A dealer shall not sell, provide, or make available to any person a live random source dog or cat unless the dealer provides the recipient of the dog or cat with certification that contains the following information:

(1) The name, address, USDA license number, and signature of the dealer;

(2) The name, address, USDA license or registration number, if such number exists, and signature of the recipient of the dog or cat;

(3) A description of each dog or cat being sold, provided, or made available that shall include:

(i) The species and breed or type (for mixed breeds, estimate the two dominant breeds or types);

(ii) The sex;

(iii) The date of birth or, if unknown, then the approximate age;

(iv) The color and any distinctive markings; and

(v) The Official USDA-approved identification number of the animal. However, if the certification is attached to a certificate provided by a prior dealer which contains the required description, then only the official identification numbers are required;

(4) The name and address of the person, pound, or shelter from which the dog or cat was acquired by the dealer, and an assurance that the person, pound, or shelter was notified that the cat or dog might be used for research or educational purposes;

(5) The date the dealer acquired the dog or cat from the person, pound, or shelter referred to in paragraph (b)(4) of this section; and

(6) If the dealer acquired the dog or cat from a pound or shelter, a signed statement by the pound or shelter that it met the requirements of paragraph (a) of this section. This statement must at least describe the animals by their official USDA identification numbers. It may be incorporated within the certification if the dealer makes the certification at the time that the animals

are acquired from the pound or shelter or it may be made separately and attached to the certification later. If made separately, it must include the same information describing each animal as is required in the certification. A photocopy of the statement will be regarded as a duplicate original.

(c) The original certification required under paragraph (b) of this section shall accompany the shipment of a live dog or cat to be sold, provided, or otherwise made available by the dealer.

(d) A dealer who acquires a live dog or cat from another dealer must obtain from that dealer the certification required by paragraph (b) of this section and must attach that certification (including any previously attached certification) to the certification which he or she provides pursuant to paragraph (b) of this section (a photocopy of the original certification will be deemed a duplicate original if the dealer does not dispose of all of the dogs or cats in a single transaction).

(e) A dealer who completes, provides, or receives a certification required under paragraph (b) of this section shall keep, maintain, and make available for APHIS inspection a copy of the certification for at least 1 year following disposition.

(f) A research facility which acquires any live random source dog or cat from a dealer must obtain the certification required under paragraph (b) of this section and shall keep, maintain, and make available for APHIS inspection the original for at least 3 years following disposition.

(g) In instances where a research facility transfers ownership of a live random source dog or cat acquired from a dealer to another research facility, a copy of the certification required by paragraph (b) of this section must accompany the dog or cat transferred. The research facility to which the dog or cat is transferred shall keep, maintain, and make available for APHIS inspection the copy of the certification for at least 3 years following disposition.

Done in Washington, DC, this 16th day of July 1993.

Eugene Branstool,

Assistant Secretary, Marketing and Inspection Services.

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NUCLEAR REGULATORY COMMISSION

10 CFR Parts 30 and 35

RIN 3150-AE58

Prepare Radiopharmaceutical Reagent Kits and Elute Radiopharmaceutical Generators; Use of Radiopharmaceuticals for Therapy; Extension of Expiration Date

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule; Extension of expiration date.

SUMMARY: The Nuclear Regulatory Commission (NRC) is extending the expiration date of the interim final rule related to the preparation and therapeutic use of radiopharmaceuticals from August 23, 1993, to December 31, 1994. The action allows licensees to continue to use byproduct material under the provisions of the interim final rule until the NRC completes a related rulemaking to address broader issues for the medical use of byproduct material (including those issues addressed by the interim final rule). The NRC expects that this broader rule would be completed and issued as a final rule before the end of 1994. This extension of the expiration date is necessary to maintain the relief provided by the interim final rule.

EFFECTIVE DATE: August 23, 1993.

FOR FURTHER INFORMATION CONTACT: Dr. Anthony N. Tse, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 492-3797.

SUPPLEMENTARY INFORMATION:

Background

On June 5, 1989, the American College of Nuclear Physicians (ACNP) and the Society of Nuclear Medicine (SNM) submitted a petition for rulemaking (PRM-35-9), requesting the Commission to amend its regulations to permit licensed nuclear pharmacists and physicians greater flexibility in the preparation and use of radiopharmaceuticals. After reviewing the petition and consulting with the U.S. Food and Drug Administration (FDA), the NRC determined that some issues raised in the petition needed to be resolved expeditiously.

Subsequently, on August 23, 1990 (55 FR 34513), the Commission published an interim final rule in the Federal Register to allow medical use licensees, under certain conditions and limitations, to use therapeutic radiopharmaceuticals for indications