Proposed Rules

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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 Parts 1 and 2

[Docket No. 00–005–1]

Animal Welfare; Definitions for and Reporting of Pain and Distress

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Request for comments.

SUMMARY: We are considering several changes to the Animal Welfare regulations to promote the humane treatment of live animals used in research, testing, and teaching and to improve the quality of information we report to Congress concerning animal pain and distress. Specifically, we are considering adding a definition for the term ''distress.'' Although this term is used throughout the Animal Welfare regulations, it is not defined. The addition of such a definition would clarify what we consider to be ''distress'' and could help assist research facilities to recognize and minimize distress in animals in accordance with the Animal Welfare Act (AWA).

We are also considering replacing or modifying the system we use to classify animal pain and distress. Professional standards regarding the recognition and relief of animal pain and distress have changed significantly since we established our classification system. Some biomedical research professionals and animal welfare advocates believe our classification system is outdated and inadequate. A different categorization system could produce data that more accurately depict the nature of animal pain or distress and provide a better tool to measure efforts made to minimize animal pain and distress at research facilities.

We are soliciting public comments on the changes we are considering. We are also interested in obtaining information on specific pain and distress classification systems other than the one we now use.

DATES: We invite you to comment on this docket. We will consider all comments that we receive by September 8, 2000.

ADDRESSES: Please send your comment and three copies to: Docket No. 00–005–1, Regulatory Analysis and Development, PPD, APHIS, Suite 3C03, 4700 River Road, Unit 118, Riverdale, MD 20737–1238.

Please state that your comment refers to Docket No. 00–005–1. 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. Jodie Kulpa, Staff Veterinarian, AC, APHIS, 4700 River Road Unit 84, Riverdale, MD 20737–1234; (301) 734–7833.

SUPPLEMENTARY INFORMATION:

Background

Under the Animal Welfare Act (AWA) (7 U.S.C. 2131 *et seq.*), the Secretary of Agriculture is authorized to promulgate standards and other requirements regarding the humane handling, care, treatment, and transportation of certain animals by dealers, research facilities, exhibitors, carriers and intermediate handlers. The Secretary has delegated responsibility for administering the AWA to the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA). Regulations established under the AWA are contained in the Code of Federal Regulations (CFR) in title 9, parts 1, 2, and 3 (referred to below as the regulations). Part 1 contains definitions for terms used in parts 2 and 3. Part 2 contains general requirements for regulated parties. Part 3 contains specific requirements for the care and handling of certain animals.

We are soliciting comments on an approach, discussed below, for amending the regulations by defining ''distress'' in part 1 and by modifying or replacing the animal pain and distress classification system in part 2.

Definition for Distress

In the regulations, we define a ''painful procedure'' as 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. Although we use the term ''distress'' in this definition and elsewhere in the regulations, there is no definition for distress in the regulations. We are considering adding such a definition because of requests from the biomedical research community and animal advocacy groups. These parties have asked USDA to provide guidance on what is considered to be distress in a procedure involving research animals in order to improve recognition of animal distress, to classify and report it more accurately, and to create a heightened awareness of the regulations' requirement to minimize animal distress and pain.

Pain and Distress Classification System

Section 13(a)(7)(B) of the AWA requires research facilities to annually provide ''information on procedures likely to produce pain or distress in any animal.'' In accordance with the AWA, the regulations at § 2.36 require facilities that use or intend to use live animals for research, tests, experiments, or teaching to submit an annual report to the Animal Care Regional Director for the State where the facility is located. Among other things, the report must state the common names and the numbers of animals upon which teaching, experiments, research, surgery, or tests were conducted involving: (1) No pain, distress, or use of pain-relieving drugs; (2) accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used; and (3) accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests.

To provide these data, each research facility must assess the potential for animal pain or distress associated with the proposed procedures. This assessment is performed prospectively (*i.e.,* before the procedure) and typically forms the basis for the pain and distress report provided by the facility to USDA. The assessment, therefore, is an estimate based on professional judgment, knowledge, and experience, and the resulting report may or may not accurately reflect the conditions the animals actually experience. The research facility can, as an option, retrospectively (*i.e.,* during or after the procedure) assess the animal pain and distress observed and report these results. We do not know how often facilities perform retrospective reporting.

There is no provision in the current classification system to address some areas identified by the research community and animal advocacy groups. For example, the current system does not include a means to report:

- An assessment of the relative intensity or duration of pain or distress either observed in the animal or anticipated to be experienced by the animal;
- An assessment of the anticipated or observed efficacy of the pain- or distress-relieving agent provided to animals undergoing a painful or distressful procedure;
- A distinction between procedures causing animal pain and procedures causing animal distress;
- Animals that were prevented from experiencing pain or distress by the appropriate and effective use of pain- or distress-relieving methods or procedures (*e.g.,* well-anesthetized animals that undergo terminal surgery);
- Animals that did not experience pain or distress due to the appropriate and effective use of pain- or distress-relieving methods or procedures other than anesthetic, analgesic, or tranquilizing agents;
- Animals that experience unrelieved pain or distress for a reason other than that the use of anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, experiments, surgery, or tests; or
- Animals that experience pain or distress without having been used in a procedure (*e.g.,* illness in animals that have been genetically altered to develop disease).

We are aware of several alternative pain and distress classification systems. For example, the system adopted by the Canadian Council on Animal Care, ''Categories of Invasiveness in Animal Experiments,'' may be viewed on the Internet at http://www.ccac.ca/english/categ.htm. The system proposed by the Humane Society of the United States may be viewed on the Internet at http://hsus.org/programs/research/usda_proposed_scale.html.[1] Other classification systems, varying greatly in complexity, are in use in other countries, such as Switzerland and Sweden.

Modifying the current USDA system, in lieu of replacing it, could also be an option. This could involve replacing or redefining the existing categories to:

- Separately report pain and distress;
- Quantify pain and distress intensity and duration;
- Separately classify anesthetized or otherwise treated animals undergoing potentially painful procedures but not experiencing pain or distress; or
- Modify the system in other ways.

We invite your comments on adding a definition for distress to the regulations and replacing or modifying our animal pain and distress classification system. We are particularly interested in soliciting comments addressing the following questions:

1. Would adding a definition for distress to the regulations help institutions using animals for research, testing, or teaching better recognize, minimize, and report animal distress?
2. If a definition for distress is added to the regulations, what key elements should be included in that definition?
3. What are the benefits and limitations of our pain and distress classification system?
4. Should our animal pain and distress classification system be modified or replaced? If so, what specific modifications or alternate classification systems should we consider?
5. Should animal pain and distress be prospectively or retrospectively reported?

Written comments should be submitted within the 60-day comment period specified in this document (see **DATES** and **ADDRESSES**).

Executive Order 12866

This action has been reviewed under Executive Order 12866. The action 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.

[1] If you do not have access to the Internet, you may obtain a copy of the system adopted by Canadian Council on Animal Care or the system proposed by the Humane Society of the United States by contacting the person listed under **FOR FURTHER INFORMATION CONTACT** at the beginning of this document.

Authority: 7 U.S.C. 2131–2159; 7 CFR 2.22, 2.80, and 371.2(g).

Done in Washington, DC, this 3rd day of July 2000.

Bobby R. Acord,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 00–17280 Filed 7–7–00; 8:45 am]

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NUCLEAR REGULATORY COMMISSION

10 CFR Part 54

[Docket No. PRM–54–1]

Union of Concerned Scientists; Receipt of Petition for Rulemaking

AGENCY: Nuclear Regulatory Commission.

ACTION: Petition for rulemaking; Notice of receipt.

SUMMARY: The Nuclear Regulatory Commission (NRC) has received and requests public comment on a petition for rulemaking filed by the Union of Concerned Scientists (petitioner). The petition has been docketed by the Commission and has been assigned Docket No. PRM–54–1. The petitioner requests that the NRC regulations governing requirements for renewal of operating licenses for nuclear power plants be amended to address potential concerns about aging degradation of liquid and gaseous radioactive waste systems. The petitioner believes the degradation from aging of piping and components of liquid and gaseous radioactive waste systems at nuclear power facilities may result in an increased probability and/or consequences from design and licensing bases events.

DATES: Submit comments by September 25, 2000. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments received on or before this date.

ADDRESSES: Submit comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Attention: Rulemaking and Adjudications staff.

Deliver comments to 11555 Rockville Pike, Rockville, Maryland, between 7:30 am and 4:15 pm on Federal workdays.

For a copy of the petition, write: David L. Meyer, Chief, Rules and Directives Branch, Division of Administrative Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. Documents related to this action