Adoption of the Ag Guide will not reduce any of the requirements in the current regulations, nor will any recommendations in the guide supersede the requirements of the regulations. Regarding the example given above, there may be times when it is scientifically justified under a research protocol to restrict an animal's space. Such exceptions to the regulatory requirements can be made with approval by a research facility's Institutional Animal Care and Use Committee. In other cases, regulated entities will be expected to comply with the requirements of the regulations, regardless of any recommendations in the Ag Guide or any other reference material.

One commenter criticized the use of the phrase ''professional judgment'' throughout the Ag Guide and said the guide's use of the word ''must'' is too limited.

The Ag Guide is a guide, not a regulation. Our adoption of these guides is intended only to offer guidance to regulated entities.

One commenter said the Ag Guide's recommendations on feeding and watering during transportation are inadequate.

The regulations in § 3.139 contain food and water requirements for farm animals during transportation. The regulations require that animals be offered potable water within 4 hours prior to being transported and that they be provided with potable water at least every 12 hours after transportation is initiated. The regulations also require, with a few exceptions, that all animals be fed at least once in every 24-hour period. We find nothing in the Ag Guide in contradiction of these requirements. Nevertheless, the requirements of the regulations are the requirements that must be met by regulated entities, and nothing in the guide can be used to allow less stringent requirements than those in the regulations.

Several commenters were concerned with the Ag Guide's acceptance of certain practices that may cause discomfort or some pain; for example, beak trimming, comb trimming, dehorning, and tail docking.

The examples given by commenters are established standard animal husbandry practices. Employment of these practices is changing, and there is increased consideration among regulated entities regarding the use of local anesthetics and the development of methods that minimize discomfort for the animals. The Ag Guide encourages methods, including anesthesia and recommendations on optimum ages for these procedures, to minimize pain and discomfort in the animals.

One commenter was concerned that the public was never given an opportunity to provide comments on the current edition of the Ag Guide prior to its being finalized.

The Ag Guide is not published by APHIS and, therefore, we have no control over whether the public is able to comment on its content prior to it being finalized. We have, however, given the public opportunity to comment on our adoption of the content of the Ag Guide.

In our notice, we said that any institution that receives funding from the National Institutes of Health (NIH) or that is accredited by an organization such as the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International) must use the Ag Guide and the ILAR Guide. One commenter said that this is incorrect. The commenter said that NIH and AAALAC International both mandate the use of the ILAR Guide, but that NIH does not mandate use of the Ag Guide, and AAALAC International uses the Ag Guide selectively.

The commenter is correct in pointing out that the Ag Guide is cited as a resource by both organizations, but its use is not mandated as a requirement for receiving funding. We wish to correct our inadvertent misstatement. We should note that AAALAC International referenced the previous version of the Ag Guide only selectively, but has adopted the revised (1999) version of the Ag Guide as a reference in its entirety.

One commenter said that APHIS should inspect AAALAC International-accredited research facilities between AAALAC International inspections in order to reduce the inspection frequency for such facilities. The commenter said the facilities could assure APHIS annually that they remain fully accredited and submit the date of the last AAALAC International inspection.

This comment is not relevant to the adoption of the ILAR Guide and the Ag Guide. Nevertheless, we offer the following response. AAALAC International conducts site visits of accredited facilities at approximately 3-year intervals. The AWA mandates that we inspect research facilities at least once each year. APHIS' inspections are unannounced to ensure we are able to view the facility as it is normally operated. At this time, we believe any effort to coordinate our inspections with the inspections of another institution may compromise our ability to conduct inspections unannounced.

Based on the rationale given in the March 3 notice and in this document, we are adopting the Ag Guide and the ILAR Guide to assist regulated entities in meeting the standards in the regulations as they apply to the handling, care, treatment, and transportation of farm animals used for nonagricultural purposes.

Done in Washington, DC, this 27th day of January 2000.

Bobby R. Acord,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 00–2382 Filed 2–2–00; 8:45 am]

BILLING CODE 3410–34–U

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. 99–069–1]

Public Meeting; Animal Care

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of public meeting.

SUMMARY: The Animal and Plant Health Inspection Service plans to hold a public meeting to discuss issues related to the humane care and treatment of exhibition animals regulated under the Animal Welfare Act.

DATES: The public meeting will be held on Tuesday, March 7, 2000, beginning at 8:30 a.m. and ending at 5p.m. On-site registration and sign-in for preregistered participants will take place from 7 a.m. to 8:30 a.m.

ADDRESSES: The public meeting will be held at the USDA Conference Center, 4700 River Road, Riverdale, MD.

FOR FURTHER INFORMATION CONTACT: Animal Care, APHIS, 4700 River Road Unit 84, Riverdale, MD 20737–1234; (301) 734–7833.

SUPPLEMENTARY INFORMATION: The Animal and Plant Health Inspection Service (APHIS) will hold a public meeting in Riverdale, MD, on March 7, 2000, to exchange information with the public about the humane care and treatment of exhibition animals regulated under the Animal Welfare Act. The meeting will include a general session followed by four workshops to run concurrently. The workshops will be offered twice, based on the public's response, to allow for increased participation. The tentative agenda for the public meeting is as follows:

8:30 a.m.–10 a.m.—General Session

10 a.m.–10:30 a.m.—Break

10:30 a.m.–12:30 p.m.—Workshops Session I

12:30 p.m.–1:30 p.m.—Lunch Break
1:30 p.m.–3:30 p.m.—Workshops Session II
3:30 p.m.–4 p.m.—Break
4 p.m.–5 p.m.—General Session/Wrap-up

The morning general session will include updates by U.S. Department of Agriculture (USDA) officials on current Animal Welfare Act issues and program initiatives focusing on, but not limited to, exhibition animal issues. Time will be allotted during the morning general session for open dialogue between USDA and the public. We are tentatively scheduling the following workshop topics:

1. Zoos
2. Circuses
3. Dealers, Research, and Transportation
4. Training and Handling of Potentially Dangerous Animals

Animal Care personnel will present information on issues related to the workshop topics and allow for discussion with the public led by an APHIS facilitator.

Workshop Issues

You may submit issues that you want presented by Animal Care during the workshops. Please specify the issue and the related workshop topic and submit no later than February 15, 2000, to Animal Care, Attention: Public Meeting, APHIS, 4700 River Road Unit 84, Riverdale, MD 20737–1234; or by fax at either (301) 734–4978 or (301) 734–4993.

Advance Registration

Advance registration is requested by February 29, 2000. Although advance registration is not required, attendance may be limited based on public response and conference center accommodations. There is no registration fee.

An advance registration form is printed below. Alternatively, an advance registration form is available via the Internet on Animal Care's home page at http://www.aphis.usda.gov/ac. Please fill out the form completely and submit it either by mail to Animal Care, Attention: Public Meeting, APHIS, 4700 River Road Unit 84, Riverdale, MD 20737–1234; or by fax at either (301) 734–4978 or (301) 734–4993.

If you have any questions about registration, contact Sue Gallagher, Program Specialist, Animal Care, on (301) 734–8877.

To: _____
No. of pages: _____
Date: _____

Advance Registration Form

Animal Care Public Meeting

March 7, 2000; 8:30 a.m.–5:00 p.m., 4700 River Road, Riverdale, MD 20737

Advance registration requested by February 29, 2000 (no fee required)

Name: _____
Organization: _____
Address: _____
_____
Phone: _____
Fax: _____

Please indicate the workshop you plan to attend during each workshops session (topics are subject to change):

10:30 a.m.–12:30 p.m.

—Zoos
—Circuses
—Dealers, Research, and Transportation
—Training and Handling of Potentially Dangerous Animals

1:30 p.m.–3:30 p.m.

—Zoos
—Circuses
—Dealers, Research, and Transportation
—Training and Handling of Potentially Dangerous Animals

Please either:

• Fax completed registration form to (301) 734–4978 or (301) 734–4993, or
• Mail completed registration form to Animal Care, Attn: Public Meeting, 4700 River Road Unit 84, Riverdale, MD 20737–1234.

For questions concerning registration, contact Sue Gallagher at (301) 734–8877.

If you require special accommodations, such as a sign language interpreter, for the meeting, please indicate below:

_____
_____
_____

Travel Information

If traveling to the metro area by air, Baltimore-Washington International (BWI) and Ronald Reagan National Airports are each located within a 1-hour drive from the USDA Center. Dulles International Airport is located within a 1½-hour drive from the USDA Center. Airport shuttle services are available via independent contracted service fleets. Check with your hotel desk for additional shuttle or taxi information, or phone Super Shuttle (servicing BWI, Ronald Reagan National, and Dulles International Airports) at (800) 258–3826 or (410) 859–0803, or Airport Connection (servicing BWI Airport) at (800) 284–6066 or (301) 352–2400.

The USDA Center is located less than 1 mile from the College Park-University of Maryland metro rail station (Green Line toward Greenbelt). Bus service is provided between the College Park-University of Maryland station and the USDA Center by both metro bus (F6 and R12 bus lines) and certain University of Maryland shuttle buses. The fee for the metro bus is $1.10. The University of Maryland shuttle bus is free.

If traveling by car, please note that a fee of $2 is required to enter the parking lot at the USDA Center. The machine takes $1 bills or quarters.

Travel directions and information are available via the Internet at Animal Care's homepage at http://www.aphis.usda.gov/ac.

Security Procedures

Upon entering the building, visitors should inform security personnel that they are attending the Animal Care public meeting. Identification is required. Security personnel will direct visitors to the registration tables located outside the conference center on the first floor. Registration is necessary for all participants, including those registered in advance. Visitor badges must be worn throughout the day.

Lodging Information

We encourage out-of-town participants to make reservations as soon as possible due to potential peak volumes at local hotels at the time of the meeting. Rooms at all hotels are on a space available basis. The following hotels are located in the Riverdale area: Greenbelt Holiday Inn, 7200 Hanover Drive, Greenbelt, MD 20770, (800) 280–4188, (301) 982–7000.

A limited number of rooms have been reserved until February 21, 2000, at a rate of $84 plus tax at the Greenbelt Holiday Inn. You must identify yourself as a ''USDA Animal Care'' attendee when making reservations. Hotel shuttle service is available to and from the USDA Center. Make arrangements with the Holiday Inn front desk: College Park Holiday Inn, 10000 Baltimore Boulevard, College Park, MD 20740, (800) 465–4329, (301) 345–6700.

A limited number of rooms have been reserved until February 21, 2000, at a rate of $89 plus tax at the College Park Holiday Inn. You must identify yourself as an ''Animal Care Public Meeting'' or ''ACP'' attendee when making reservations. Hotel shuttle service is available to and from the USDA Center. Make arrangements with the Holiday Inn front desk: Greenbelt Courtyard-Marriott, 6301 Golden Triangle Drive, Greenbelt, MD 20770, (800) 321–2211, (301) 441–3311.

There are no special lodging rates offered at the Greenbelt Courtyard-Marriott, and no shuttle service is available to the USDA Center.

Please check with your travel agent for other hotel availability.

Authority: 7 U.S.C. 2131 *et seq.*

Done in Washington, DC, this 28th day of January 2000.

Bobby R. Acord,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 00–2383 Filed 2–2–00; 8:45 am]

BILLING CODE 3410–34–U

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. 99–068–1]

Draft Guideline on Stability Testing of Biotechnological/Biological Veterinary Medicinal Products, VICH Topic GL17

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of availability and request for comments.

SUMMARY: A draft guideline titled ''Stability Testing of Biotechnological/Biological Veterinary Medicinal Products'' has been developed by the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). The guideline contains proposed international standards for the generation and submission of stability data for products such as cytokines (interferons, interleukins, colony-stimulating factors, tumor necrosis factors), monoclonal antibodies, and vaccines consisting of well-characterized proteins or polypeptides, including some conventional vaccines. Because the draft guidelines pertain to veterinary biological products regulated by the Animal and Plant Health Inspection Service under the Virus-Serum-Toxin Act, we are requesting comments on its provisions so that we may include any relevant public input on the draft in the Agency's comments to the VICH Steering Committee.

DATES: We invite you to comment on the draft guidelines. We will consider all comments that we receive by April 3, 2000.

ADDRESSES: Please send your comment and three copies to: Docket No. 99–068–1, 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. 99–068–1.

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 rules, are available on the Internet at http://www.aphis.usda.gov/ppd/rad/webrepor.html.

You may request a copy of the draft ''Stability Testing of Biotechnological/Biological Veterinary Medicinal Products'' by writing to or calling the person listed under **FOR FURTHER INFORMATION CONTACT**.

FOR FURTHER INFORMATION CONTACT: Dr. Albert P. Morgan, CVB-LPD, VS, APHIS, 4700 River Road Unit 148, Riverdale, MD 20737–1231; phone (301) 734–8245.

SUPPLEMENTARY INFORMATION: The International Cooperation on Harmonization of Technical Requirements for the Registration of Veterinary Medicinal Products (VICH) is a unique project conducted under the auspices of the International Office of Epizootics (OIE, the Office International des Epizooties) that brings together the regulatory authorities of the European Union, Japan, and the United States and representatives from the animal health industry in the three regions. The purpose of VICH is to harmonize technical requirements for veterinary products (both drugs and biologics). Regulatory authorities and industry experts from Australia and New Zealand participate in an observer capacity. The World Federation of the Animal Health Industry (COMISA, the Confederation Mondiale de L'Industrie de la Sante Animale) provides the secretarial and administrative support for VICH activities.

The United States Government is represented in VICH by the Food and Drug Administration (FDA) and the Animal and Plant Health Inspection Service (APHIS). The FDA provides expertise regarding veterinary drugs, while APHIS fills a corresponding role for veterinary biological products. As VICH members, APHIS and FDA participate in efforts to enhance harmonization and have expressed their commitment to seeking scientifically based harmonized technical requirements for the development of veterinary drugs and biological products. One of the goals of harmonization is to identify and reduce the differences in technical requirements for veterinary drugs and biologics among regulatory agencies in different countries.

The draft document that is the subject of this notice, ''Stability Testing of Biotechnological/Biological Veterinary Medicinal Products'' (VICH Topic GL17), has been made available by the VICH Steering Committee for comments by interested parties. The guideline is intended to function as an international standard for the generation and submission of stability data for products such as cytokines (interferons, interleukins, colony-stimulating factors, and tumor necrosis factors), monoclonal antibodies, and vaccines consisting of well-characterized proteins or polypeptides. Because the guideline pertains to some veterinary biological products regulated by APHIS under the Virus-Serum-Toxin Act—particularly with regard to prelicensing stability studies—we are requesting comments on its provisions so that we may include any relevant public input on the draft in the Agency's comments to the VICH Steering Committee.

The draft document pertains to the generation and submission of studies testing the stability of veterinary biological products that consist of well-characterized proteins and polypeptides, their derivatives, and products of which they are components. (The draft guideline refers to such studies as ''stability studies.'') In accordance with the VICH process, once a final draft of ''Stability Testing of Biotechnological/Biological Veterinary Medicinal Products'' has been approved, the guideline will be recommended for adoption by the regulatory bodies of the European Union, Japan, and the United States. As with all VICH documents, the final guideline will not create or confer any rights for or on any person and will not operate to bind APHIS or the public. Further, the VICH guidelines specifically provide for the use of alternative approaches if those approaches satisfy applicable regulatory requirements.

Ultimately, APHIS intends to consider the VICH Steering Committee's final guidance document for use by U.S. veterinary biologics licensees, permittees, and applicants. In addition, APHIS will consider its use as a basis for the approval of stability studies conducted to establish and extend expiration dates for applicable veterinary biological products under 9 CFR 114.13 and 114.14. APHIS may also use the final guidance document as the basis for proposed additions or amendments to its regulations in 9 CFR